UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

KENTUCKY RIVER DISTRICT HEALTH DEPARTMENT, and all others similarly situated,

Plaintiffs,

v.

PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC.; NORAMCO, INC.; ENDO HEALTH SOLUTIONS, INC.; ENDO PHARMACEUTICALS, INC.; AMNEAL PHARMACEUTICALS, LLC; MALLINCKRODT PLC; MALLINCKRODT, LLC; SPECGX, LLC; ALLERGAN PLC f/k/a ACTAVIS PLC; ACTAVIS, LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; WATSON LABORATORIES, INC.; DEPOMED, INC.; MCKESSON CORPORATION; ANDA, INC.; CARDINAL HEALTH, INC.; H.D. SMITH, LLC f/k/a H.D. SMITH WHOLESALE DRUG CO.; AMERISOURCEBERGEN DRUG CORPORATION; RICHIE PHARMACAL CO.; MYLAN PHARMACEUTICALS, INC.; SANDOZ, INC., OMNICARE DISTRIBUTION CENTER, LLC; PAR PHARMACEUTICAL; HIKMA PHARMACEUTICALS PLC; QUEST PHARMACEUTICALS, INC.; INDIVIOR PLC; and DOES 1-100,

Defendants.

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

MDL No. _____

This Action Relates to:
Case No. 17-md-2804
Hon. Dan A. Polster

CLASS-ACTION COMPLAINT

JURY TRIAL DEMANDED

COMPLAINT

COME NOW Plaintiff Kentucky River District Health Department, by and through counsel, and on behalf of itself and all others similarly situated (hereinafter "Plaintiffs") hereby bring this class-action Complaint against the above-named Defendants, alleging as follows:

I. INTRODUCTION

1. Plaintiff Kentucky River District Health Department (hereinafter "Plaintiff" or "Kentucky River"), like other similar situated Kentucky local health departments, is a vital link to the rural communities it serves.

2. Kentucky River, on behalf of itself and all others similarly situated, brings this civil action to eliminate the hazard to public health and safety caused by the opioid epidemic, to abate the nuisance caused thereby, and to recoup monies that have been spent, or will be spent, because of Defendants' false, deceptive, and unfair marketing and/or unlawful diversion of prescription opioids.[1] Such economic damages were foreseeable to Defendants and were sustained because of Defendants' intentional and/or unlawful actions and omissions.

3. Opioid analgesics are widely diverted and improperly used, and the widespread abuse of opioids has resulted in a national epidemic of opioid overdose deaths and addictions.[2]

4. The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[3]

5. Plaintiffs bring this suit against the manufacturers of prescription opioids. The manufacturers aggressively promoted and pushed highly addictive, dangerous opioids, falsely

[1] As used herein, the term "opioid" refers to the entire family of opiate drugs including natural, synthetic, and semi-synthetic opiates.
[2] *See* Nora D. Volkow & A Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 N. Engl. J. Med. 1253 (2016).
[3] *See* Robert M. Califf, *et al*., *A Proactive Response to Prescription Opioid Abuse*, 374 N. Engl. J. Med. 1480 (2016).

representing to doctors that patients would rarely succumb to drug addiction. These pharmaceutical companies aggressively advertised to and persuaded doctors to prescribe highly addictive, dangerous opioids—turning patients into drug addicts for their own corporate profit. Such actions were intentional and unlawful.

6. Plaintiffs also bring this suit against the wholesale distributors of these highly addictive drugs. The distributors and manufacturers intentionally and/or unlawfully breached their legal duties under federal and State law to monitor, detect, investigate, refuse, and report suspicious orders of prescription opioids.

II. THE PARTIES

A. Plaintiffs

7. Kentucky River is a District Health Department serving Knott, Lee, Leslie, Letcher, Owsley, Perry, and Wolfe counties. It is the mission of Kentucky River to protect, maintain, and promote the health of the people of its communities. Kentucky River operates a variety of preventive health programs for children and adults to ensure the good health of its citizens and acts as a source of information and services for individuals and families who need assistance with medical care, nutritional counseling, health screening, immunizations, family planning, and environmental protection.

8. As a direct and proximate result of Defendants' conduct, Kentucky River has suffered actual injury and damages including, but not limited to, significant increased expenses for providing public health services, including but not limited to: (1) providing vaccinations and public health services related to public outbreaks of HIV, Hepatitis A, B, and C; (2) administering and operating needle exchange programs; (3) providing public safety relating to the opioid epidemic; (4) providing public health educational programs on

preventing opioid addiction, abuse, and/or dependency; (5) providing prenatal services to infants and mothers with opioid-related medical conditions; (6) providing services for at least the first two years of a child's life, to children born with opioid-related medical conditions and children whose families suffer from opioid-related disabilities or incapacitation; and (7) providing services for at least the first two years of a child's life, to mothers and families of children suffering from opioid-related medical conditions. While Kentucky River normally has some expenses related to these services, the expenses have been significantly increased as a direct and proximate result of Defendants' conduct, and thus constitute specific and special injuries. The increased expenditures have been a necessary means to respond to issues created by unlawful opioid prescription drugs in Kentucky River's communities, but much greater expenditures are needed to abate the serious problems caused by the opioid epidemic.

9. Kentucky River seeks the means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct. Kentucky River is authorized by law to abate any nuisance and prosecute in any court of competent jurisdiction any person who creates, continues, contributes to, or suffers such nuisance to exist and prevent injury and annoyance from such nuisance.

10. Kentucky River brings this action on behalf of itself and on behalf of all other similarly situated Kentucky District, Independent, County, Urban-County, and City-County Health Departments that have suffered financial damages as a result of the ongoing opioid epidemic. (*See* KRS §§ 212.810- 212.930; 212.780-212.794; 212.020-212.275; 212.626-212.639; 212.640-212.710.)

11. Plaintiffs have standing to sue and to recover damages incurred as a result of Defendants' actions and omissions. Plaintiffs have standing to bring all claims pled herein.

B. Defendants

1. The Manufacturer and Marketing Defendants

a. Purdue and Associated Companies

12. Defendant Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut.

13. Defendant Purdue Pharma Inc. is a New York corporation with its principal place of business in Stamford, Connecticut.

14. Defendant The Purdue Frederick Company, Inc. is a New York corporation with its principal place of business in Stamford, Connecticut. Defendants Purdue Pharma, L.P., Purdue Pharma, Inc. and The Purdue Frederick Company, Inc. are collectively referred to as "Purdue."

15. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in in Plaintiffs' Communities, throughout Kentucky, and throughout the nation. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual nationwide sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers). OxyContin is Purdue's largest-selling opioid, in both the Plaintiffs' communities and the nation. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

16. In 2007, Purdue settled criminal and civil charges against it for misbranding OxyContin and agreed to pay the United States $635 million—at the time, one of the largest settlements with a drug company for marketing misconduct. Pursuant to its settlement, Purdue

operated under a Corporate Integrity Agreement with the Office of Inspector General of the U.S. Department of Health and Human Services, which required the company, inter alia, to ensure that its marketing was fair and accurate, and to monitor and report on its compliance with the Agreement. None of this stopped Purdue. In fact, Purdue continued to create the false perception that opioids were safe and effective for long-term use, even after being caught using unbranded marketing methods to circumvent the system. In short, Purdue paid the fine when caught and then continued business as usual, deceptively marketing and selling billions of dollars of opioids each year.

b. Cephalon and Associated Companies

17. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania.

18. Defendant Teva Pharmaceutical Industries, Ltd. is an Israeli corporation with its principal place of business in Petah Tikva, Israel. Teva Pharmaceuticals Ltd. acquired Cephalon in October 2011, and Cephalon Inc. became a wholly owned subsidiary of Teva Pharmaceuticals Ltd.

19. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania, and is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd.

20. Teva USA and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva USA also sells generic opioids in Plaintiff's Communities, throughout Kentucky, and throughout the United States, including generic opioids previously sold by Allergan plc, whose generics business Teva Pharmaceutical Industries Ltd., Teva USA's parent

company based in Israel, acquired in August 2016. Teva USA and Cephalon, Inc. are collectively referred to herein as "Teva."

21. Teva USA and Cephalon, Inc. worked together to manufacture, promote, sell, and distribute opioids such as Actiq and Fentora in Plaintiff's Communities, throughout Kentucky, and throughout the United States. Actiq has been approved by the FDA only for the "management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain."[4] Fentora has been approved by the FDA only for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."[5] In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, and agreed to pay a $425 million fine.[6]

22. Teva USA, and Cephalon, Inc. (collectively Cephalon) work together closely to market and sell Cephalon products in Plaintiff's Communities, throughout Kentucky, and throughout the United States. Since its acquisition of Cephalon in October 2011, Teva USA has conducted all sales and marketing activities for Cephalon in the United States, through its "specialty medicines" division. Teva USA holds out Actiq and Fentora as Teva products to the

[4] *Highlights of Prescribing information, ACTIQ® (fentanyl citrate) oral transmucosal lozenge, CII (2009)*, ACTIQ PI/Med Guide, https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s030lbl.pdf (last accessed August 1, 2018).
[5] *Highlights of Prescribing Information, FENTORA® (fentanyl citrate) buccal tablet, CII (2011)*, https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021947s015lbl.pdf (last accessed August 1, 2018).
[6] Press Release, U.S. Dep't of Justice, Biopharmaceutical Company, Cephalon, to Pay $425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing (Sept. 29, 2008), https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html.

public. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events.

23. All of Cephalon's promotional websites, including those for Actiq and Fentora, display Teva Ltd.'s logo.[7] Teva USA's parent company, Teva Pharmaceuticals Industries, Ltd. lists Cephalon's and Teva USA's sales as its own on its financial reports, and its year-end report for 2012 – the year immediately following the Cephalon acquisition – attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales," including *inter alia* sales of Fentora.[8]

24. Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to herein as "Cephalon."

25. From 2000 forward, Cephalon has made thousands of payments to physicians nationwide, including in Kentucky, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, many of whom were not oncologists and did not treat cancer pain, but in fact to deceptively promote and maximize the use of opioids.

c. Janssen and Associated Companies

26. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

27. Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its

[7] *E.g.*, ACTIQ, http://www.actiq.com/ (displaying logo at bottom-left) (last accessed August 1, 2018).
[8] Teva Ltd., Annual Report (Form 20-F), at 62 (Feb. 12, 2013), http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf.

principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of J&J.

28. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which was formerly known as Janssen Pharmaceutica, Inc.

29. Defendant Noramco, Inc. is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July 2016. Noramco, Inc. is or had been part of J&J's opium processing. It makes active pharmaceutical ingredients ("APIs") for opioid painkillers.

30. Johnson & Johnson is the only company that owns over 10% of Janssen Pharmaceuticals stock. J&J controls the sale and development of Janssen Pharmaceuticals drugs and Janssen Pharmaceuticals profits inure to J&J's benefit.

31. J&J, Janssen Pharmaceuticals, Inc., Noramco, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc. (collectively, "Janssen") are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids in Plaintiff's Communities, throughout Kentucky, and throughout the United States.

32. Janssen manufactures, promotes, sells, and distributes drugs in Plaintiff's Communities, throughout Kentucky, and throughout the United States, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta (tapentadol) and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

33. Janssen made thousands of payments to physicians nationwide, including in Kentucky, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact

to deceptively promote and maximize the use of opioids.

34. Janssen, like many other companies, has a corporate code of conduct, which sets forth the organization's mission, values and principles. Janssen's employees are required to read, understand and follow its Code of Conduct for Health Care Compliance. Johnson & Johnson imposes this code of conduct on Janssen as a pharmaceutical subsidiary of J&J.[9] Documents posted on J&J's and Janssen's websites confirm J&J's control of the development and marketing of opioids by Janssen. Janssen's website "*Ethical Code for the Conduct of Research and Development*," names only J&J and does not mention Janssen anywhere within the document. The "*Ethical Code for the Conduct of Research and Development*" posted on the Janssen website is J&J's company-wide Ethical Code, which it requires all of its subsidiaries to follow.

35. The "*Every Day Health Care Compliance Code of Conduct*" posted on Janssen's website is a J&J company-wide document that describes Janssen as one of the "*Pharmaceutical Companies of Johnson & Johnson*" and as one of the "*Johnson & Johnson Pharmaceutical Affiliates.*" It governs how "[a]ll employees of Johnson & Johnson Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise Johnson & Johnson Pharmaceutical Affiliates' products." All Janssen officers, directors, employees, sales associates must certify that they have "read, understood and will abide by" the code. The code governs all of the forms of marketing at issue in this case. J&J made payments to thousands of physicians nationwide, including in Kentucky, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

[9] Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015.

d. Endo and Associates Companies

36. Defendant Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

37. Defendant Endo Pharmaceuticals Inc. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

38. Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. (collectively "Endo") are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids in Plaintiff's Communities, throughout Kentucky, and throughout the United States.

39. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, generic versions of oxycodone, oxymorphone, hydromorphone and hydrocodone in the United States. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. On June 8, 2017, the FDA requested that Endo remove Opana ER from the market because of a "serious outbreak" of HIV and hepatitis C due to abuse of the drug after the reformulation of Opana from a nasal spray to an injectable.[10] In response to the FDA's request, Endo removed Opana ER from the market in July 2017.[11] Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in Plaintiff's Communities, throughout Kentucky, and

[10] Press Release, U.S. Food & Drug Administration, FDA Requests Removal of Opana ER for Risks Related to Abuse (June 8, 2017), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm.
[11] Press Release, Endo International PLC, Endo Provides update on Opana ER (July 6, 2017), http://investor.endo.com/news-releases/news-release-details/endo-provides-update-opanar-er.

throughout the United States, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

40. Endo made thousands of payments to physicians nationwide, including in Kentucky, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

e. Amneal Pharmaceuticals, LLC

41. Defendant Amneal Pharmaceuticals, LLC ("Amneal") is a Delaware limited liability company with its principal place of in New Jersey. At all relevant times, Amneal has manufactured prescription drugs, including opioids, and has sold prescription drugs, including opioids, in Plaintiff's Communities, throughout Kentucky, and throughout the United States..

f. Mallinckrodt Entities

42. Defendant Mallinckrodt plc is an Irish public limited company with its headquarters in Staines-Upon-Thames, Surrey, United Kingdom. Mallinckrodt plc was incorporated in January 2013 for the purpose of holding the pharmaceuticals business of Covidien plc, which was fully transferred to Mallinckrodt plc in June of that year. Mallinckrodt plc also operates under the registered business name Mallinckrodt Pharmaceuticals, with its U.S. headquarters in Hazelwood, Missouri.

43. Defendant Mallinckrodt LLC (together with Mallinckrodt plc and SpecGx LLC, "Mallinckrodt") is a Delaware corporation with its headquarters in Hazelwood, Missouri. Defendant SpecGx LLC is a Delaware limited liability company with its headquarters in Clayton, Missouri and is a wholly-owned subsidiary of Mallinckrodt plc. Mallinckrodt manufactures, markets, sells and distributes pharmaceutical drugs in Plaintiff's Communities, throughout Kentucky, and throughout the United States. Mallinckrodt is the largest U.S. supplier of opioid

pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

44. Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In 2009, Mallinckrodt Inc., a subsidiary of Covidien plc, acquired the U.S. rights to Exalgo. The FDA approved Exalgo for treatment of chronic pain in 2012. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March 2014, and which Mallinckrodt has since discontinued. Mallinckrodt promoted its branded opioid products with its own direct sales force.

45. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt estimated that in 2015 it received approximately 25% of the DEA's entire annual quota for controlled substances that it manufactures. Mallinckrodt also estimated, based on IMS Health[12] data for the same period, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.[13]

46. Mallinckrodt operates a vertically integrated business in the United States: (1) importing raw opioid materials, (2) manufacturing generic opioid products, primarily at its facility in Hobart, New York, and (3) marketing and selling its products to drug distributors, specialty

[12] "IMS Health was a [provider of] information, services and technology for the healthcare industry, including U.S. physician prescribing data." It has changed its corporate form and is now known as "IQVIA."
[13] Mallinckrodt plc 2016 Form 10-K.

pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups.

47. Among the drugs Mallinckrodt manufactures or has manufactured are the following: Schedule II: Exalgo (Hydromorphone hydrochloride, extended release), Roxicodone (Oxycodone hydrochloride), Xartemis XR (Oxycodone hydrochloride and acetaminophen), Methadose (Methadone hydrochloride), Generic Morphine sulfate extended release, Morphine sulfate oral solution, Fentanyl transdermal system, Oral transmucosal fentanyl citrate, Oxycodone and acetaminophen, Hydrocodone bitartrate and acetaminophen, Hydromorphone hydrochloride, Hydromorphone hydrochloride, extended release, Oxymorphone hydrochloride, Methadone hydrochloride. Schedule III: Buprenorphine and naloxone. Unscheduled: Naltrexone hydrochloride.

48. Mallinckrodt made thousands of payments to physicians nationwide, including in Kentucky, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

g. Actavis and Associated Companies

49. Defendant Allergan plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland.

50. Defendant Actavis plc acquired Defendant Allergan plc in March 2015, however the combined company changed its name to Allergan plc in January 2013.

51. Defendant Watson Pharmaceuticals, Inc. had acquired Defendant Actavis, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013, and then changed the name to Actavis plc in October 2013.

52. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Defendant Allergan plc (f/k/a Actavis, Inc., f/k/a, Actavis PLS, f/k/a Watson Pharmaceuticals, Inc.).

53. Defendant Actavis Pharma, Inc. (f/k/a Actavis, Inc., f/k/a Watson Pharma, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc.

54. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey.

55. Each of these Defendants is owned by Defendant Allergan plc, which uses them to market and sell its drugs in Plaintiff's Communities, throughout Kentucky, and throughout the United States.

56. Defendant Allergan plc exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. Allergan plc, Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. (collectively, "Actavis") are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids in Plaintiff's Communities, throughout Kentucky, and throughout the United States.

57. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana in Plaintiff's Communities, throughout Kentucky, and throughout the United States. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

58. Actavis made thousands of payments to physicians nationwide including in

Kentucky, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

h. Depomed, Inc.

59. Defendant Depomed, Inc. ("Depomed") is a California corporation with its principal place of business in Newark, California. Depomed describes itself as a specialty pharmaceutical company focused on pain and other central nervous system conditions. Depomed develops, markets, and sells prescriptions drugs in Plaintiff's Communities, throughout Kentucky, and throughout the United States. Depomed acquired the rights to Nucynta and Nucynta ER for $1.05 billion from Janssen pursuant to a January 15, 2015, Asset Purchase Agreement. This agreement closed on April 2, 2015.

i. Indivior PLC

60. Indivior PLC ("Indivior") is a is a multinational pharmaceutical company with its headquarters in Slough, United Kingdom, and its principal place of business in the United States located in Richmond, Virginia. Indivor manufactures opioids and sells opioids in Plaintiff's Communities, throughout Kentucky, and throughout the United States.

61. Collectively, the Defendants specified in Paragraphs 12-60, above, are referred to as the "Marketing Defendants."

2. The Distributor Defendants

62. The Distributor Defendants are identified below. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes.

63. The Distributor Defendants universally failed to comply with federal and Kentucky law. The Distributor Defendants are engaged in "wholesale distribution," as defined under Kentucky law. Plaintiff alleges the unlawful conduct by the Distributor Defendants is a substantial cause for the volume of prescription opioids plaguing Plaintiffs' communities.

a. McKesson Corporation

64. McKesson Corporation ("McKesson") at all relevant times operated as a licensed pharmacy wholesaler in Plaintiffs' communities. McKesson is a Delaware corporation. McKesson's principal place of business is in San Francisco, California. At atll relevant times, McKesson distributed opioids in Plaintiff's Communities, throughout Kentucky, and throughout the United States.

b. Anda, Inc.

65. Defendant Anda, Inc., ("Anda") through its various DEA registrant subsidiaries and affiliated entities, including but not limited to, Anda Pharmaceuticals, Inc., is the fourth largest distributor of generic pharmaceuticals in the United States. Anda is a Florida corporation with its principal place of business in Weston, Florida. In October 2016, Defendant Teva acquired Anda from Allergan plc (i.e. Defendant Actavis), for $500 million in cash. At all times relevant to this Complaint, Anda distributed prescription opioids throughout the United States, including in Kentucky, and within the communities served by Plaintiffs.

c. Cardinal Health, Inc.

66. Defendant Cardinal Health, Inc. ("Cardinal") is an Ohio Corporation with its principal place of business in Dublin, Ohio. In 2016, Cardinal generated revenues of $121.5 billion.

67. Cardinal is a global distributor of pharmaceutical drugs and medical products. It is one of the largest distributors of opioids in the United States. It has annual resources of over $120

billion. Additionally, in December 2013, Cardinal formed a ten-year agreement with CVS Caremark to form the largest generic drug sourcing operation in the United States. Cardinal has, at all relevant times, had distribution centers throughout the United States, including Kentucky, and has distributed in Plaintiff's Communities, throughout Kentucky, and throughout the United States.

d. H.D. Smith, LLC

68. Defendant H. D. Smith, LLC f/k/a H. D. Smith Wholesale Drug Co. ("H. D. Smith") through its various DEA registered subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes opioids throughout the United States, including Kentucky and the community served by Plaintiffs. H. D. Smith is a privately held independent pharmaceuticals distributor of wholesale brand, generic and specialty pharmaceuticals and is a Delaware corporation with its principal place of business in Illinois. H. D. Smith Wholesale Drug Co. has been restructured and is currently doing business of H. D. Smith, LLC's sole member is H. D. Smith Holdings, LLC, and its sole member is H. D. Smith Holding Company, a Delaware corporation with its principal place of business in Illinois. H. D. Smith is the largest independent wholesaler in the United States. In January 2018, Defendant AmerisourceBergen acquired H. D. Smith.

e. AmerisourceBergen Drug Corporation

69. Defendant AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a wholesaler of pharmaceutical drugs that distributes opioids in Plaintiff's Communities, throughout Kentucky, and throughout the United States.

70. AmerisourceBergen is the eleventh largest company by revenue in the United States, with annual revenue of $147 billion in 2016. AmerisourceBergen's principal place of

business is located in Chesterbrook, Pennsylvania, and it is incorporated in Delaware.

71. According to its 2016 Annual Report, AmerisourceBergen is "one of the largest global pharmaceutical sourcing and distribution services companies, helping both healthcare providers and pharmaceutical and biotech manufacturers improve patient access to products and enhance patient care."[14]

f. Richie Pharmacal Co.

72. Upon information and belief, Defendant Richie Pharmacal Co. ("Richie") is incorporated in Kentucky with a principal place of business in Glasgow, Kentucky.

73. Richie is a pharmaceutical distributor licensed to do business in Kentucky.

74. Richie does substantial business in the Commonwealth of Kentucky.

75. Richie distributes pharmaceuticals to retail pharmacies and institutional providers to customers in Plaintiff's Communities, throughout Kentucky, and throughout the United States.

g. Omnicare Distribution Center, LLC

76. Defendant Omnicare Distribution Center, LLC ("Omnicare") is a Delaware corporation with its principal place of business in Cincinnati, Ohio. Omnicare is a wholesale distributor of pharmaceutical drugs that distributes opioids in in Plaintiffs' Communities, throughout Kentucky, and throughout the nation.

h. Quest Pharmaceuticals, Inc.

77. Quest Pharmaceuticals, Inc. ("Quest") is a Kentucky corporation with its principal place of business in Murray, Kentucky. Quest is a distributor of pharmaceutical drugs that distributes opioids in in Plaintiffs' Communities, throughout Kentucky, and throughout the nation.

[14] AmerisourceBergen, 2016 Summary Annual Report, http://investor.amerisourcebergen.com/static-files/37daf1ed-4d41-4547-bb87-86d501087dbb (last accessed August 1, 2018).

78. Collectively, the Defendants specified in Paragraphs 62-77, above, are referred to as the "Distributor Defendants."

C. The Manufacturer, Marketing, and Distributor Defendants.

79. Defendant Mylan Pharmaceuticals, Inc. ("Mylan") is a Pennsylvania corporation with its principal place of business in Canonsburg, Pennsylvania. It manufactures, promotes, distributes, and sells opioids in in Plaintiffs' Communities, throughout Kentucky, and throughout the nation, including many Schedule II controlled substances such as Oxycodone and Propoxy-N. Mylan conducts its pharmaceutical business operations through various entities, including Mylan Speciality, LP. and Mylan Pharms Inc. (collectively "Mylan").

80. Defendant Sandoz, Inc. ("Sandoz") is a Colorado corporation with its principal place of business in Princeton, New Jersey. It manufactures, promotes, distributes, and sells opioids in in Plaintiffs' Communities, throughout Kentucky, and throughout the nation, including a product known as the Fentanyl Patch, a device to administer a time-released dosing of Fentanyl.

81. Defendant Par Pharmaceutical ("Par") is a Delaware corporation with its principle office and place located in Chestnut Ridge, New York. Par manufactures, promotes, sells, and distributes opioids in in Plaintiffs' Communities, throughout Kentucky, and throughout the nation.

82. Defendant Hikma Pharmaceticals PLC ("Hikma"), f/k/a West-Ward Pharmaceuticals, is a multinational pharmaceutical company with its headquarters in London, United Kingdom, and its principal place of business in the United States located in Eastontown, New Jersey. Hikma manufactures, promotes, sells, and distributes opioids in in Plaintiffs' Communities, throughout Kentucky, and throughout the nation.

83. Collectively, the Defendants specified in Paragraphs 79-82, above, are referred to as the "Marketing Defendants" and/or the "Distributor Defendants."

D. Defendants' Agents (Doe Defendants)

84. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment, and/or with Defendants' actual, apparent, and/or ostensible authority.

85. The true names and capacities, whether individual, corporate, associate, or otherwise of certain vendors, distributors and/or their alter egos, sued herein as DOES 1 through 100 inclusive, are presently unknown to Plaintiffs, who therefore sues these Defendants by fictitious names. Plaintiffs will seek leave of this Court to amend this Complaint to show their true names and capacities when they become ascertained. Each of the Doe Defendants has taken part in and participated with, and/or aided and abetted, some or all of the other Defendants in some or all of the matters referred to herein, and therefore are liable for the same.

III. JURISDICTION AND VENUE

86. This Court has subject-matter jurisdiction under 28 U.S.C. § 1331 because this action presents federal questions. This Court has supplemental jurisdiction over the causes of action arising under state law because these claims are part of the same case or controversy.

87. This Court has personal jurisdiction over all Defendants because each Defendant has substantial contacts and business relationships in Kentucky and has purposely availed itself of business opportunities in Kentucky, including by marketing, distributing and/or selling prescription opioids in Kentucky.

88. This Court also has personal jurisdiction over all of the Defendants under 18 U.S.C. 1965(b). This Court may exercise nationwide jurisdiction over the named Defendants where the

"ends of justice" require national service. Here, the interests of justice require that Plaintiffs be allowed to bring all members of the nationwide RICO enterprise before the court in a single trial. *See, e.g.*, *Iron Workers Local Union No. 17 Insurance Fund v. Philip Morris Inc.*, 23 F. Supp. 2d 796 (1998) (citing *LaSalle National Bank v. Arroyo Office Plaza, Ltd.*, 1988 WL 23824, *3 (N.D. Ill. Mar 10, 1988); *Butcher's Union Local No. 498 v. SDC Invest., Inc.*, 788 F.2d 535, 539 (9th Cir. 1986).

89. Venue is proper in this District pursuant to Case Management Order No. 1, which provides for direct filing in this Court for any Plaintiff whose case would be subject to transfer to this MDL.

IV. CLASS-ACTION ALLEGATIONS

90. Plaintiffs respectfully request that the Court certify their claims for class action under Rules 23(b)(2) and 23(b)(3) of the Federal Rules of Civil Procedure. This Complaint seeks relief, including compensatory, treble, and punitive damages, for Defendants' creation of a public nuisance and their violations of the Federal RICO statute, negligence, negligence per se, and unlawful and deceptive trade practices.

91. Plaintiffs seek to certify a state-wide class of all Kentucky District, Independent, County, Urban-County, and City-County Health Departments that are similarly situated and have suffered the same losses due to the opioid crisis and epidemic caused by Defendants.

92. Plaintiffs bring this action pursuant to Fed. R. Civ. P. 23. The Class meets the prerequisites for the maintenance of a class action in that:

(a) The Class is so numerous that joinder of all Class members is impractical;

(b) Nearly all factual, legal, and statutory relief issues that are raised in this Complaint are common to each of the members of the Class and apply uniformly to every member of the class;

(c) The claims of the representative Plaintiffs are typical of the claims of each member of the Class. Plaintiffs, like all other members of the Class, sustained damages arising from Defendants' violations of law, including violations of the Federal RICO Statue. The representative Plaintiff and the members of the Class were and are similarly or identically harmed by the same unlawful, deceptive, unfair, systematic, and pervasive pattern of misconduct;

(d) The representative Plaintiff will fairly and adequately represent and protect the interests of the Class. There are no material conflicts between the claims of the representative Plaintiff and the members of the Class that would make a class certification inappropriate; and

(e) The counsel selected to represent the Class will fairly and adequately protect the interests of the Class. They are experienced trial lawyers who have experience in complex litigation and are competent counsel for this class action litigation. Counsel for the Class will vigorously assert the claims of all members of the Class.

93. This action is properly maintained as a class action in that common questions of law and fact exist as to the members of the Class and predominate over any questions affecting only individual members, and a class action is superior to other available methods for the fair and efficient adjudication of the controversy, including consideration of:

(a) The interests of the members of the Class in individually controlling the prosecution or defense of separate actions;

(b) The extent and nature of any other proceedings concerning the controversy already commenced by or against members of the Class;

(c) The desirability or undesirability of concentrating the claims in a single forum; and

(d) The difficulties likely to be encountered in the management of a class action.

94. The members of the Class contemplate the eventual issuance of notice to the proposed Class members that would set forth the subject and nature of the instant action. To the extent any further notices may be required, Plaintiff contemplates the use of additional media and/or mailings.

95. Among the numerous questions of law and fact common to the Class are:

(a) Whether Defendants engaged in false, deceptive, unfair, or unlawful marketing practices in the promotion of Defendants' respective opioid products by, *inter alia*, misrepresenting the addictive nature of opioids they manufactured, marketed, and distributed;

(b) Whether Defendants knew of the risks associated with their opioid products but ignored those risks and continued to aggressively market their highly addictive opioid products;

(c) Whether Defendants violated the Federal RICO statute in the development, manufacturing, promotion, selling, and/or distribution of opioids;

(d) Whether Defendants conduct an enterprise, through mail and wire fraud, to profit from the sale of dangerous prescription opioid drugs;

(e) Whether Defendants conduct an enterprise, through the unlawful manufacture and distribution of controlled substances, to profit from the sale of dangerous prescription opioid drugs;

(f) The nature of Defendants' legal duty to design and operate a closed system to prevent the diversion of dangerous prescription opioid drugs into channels other than legitimate medical, scientific, or industrial uses;

(g) Whether Defendants breached their duty to design and operate a closed system to prevent the diversion of dangerous prescription opioid drugs into illicit channels;

(h) Whether Defendants breached their duty to halt suspicious orders of dangerous prescription opioid drugs into illicit channels;

(i) The nature and adequacy of Defendants' internal systems and standard operating procedures as they relate to identifying suspicious orders, investigating suspicious orders, reporting suspicious orders, and stopping shipment of suspicious orders of dangerous prescription opioid drugs;

(j) Defendants' knowledge of the dangers of diversion of opioid drugs into illicit channels and/or for off-label purposes;

(k) Defendants' response to, and failures to heed, the DEA's repeated warnings and instructions regarding the need to safeguard against diversion of opioids into illicit channels;

(l) Whether, and the degree to which, Defendants promoted and/or allowed the use of these drugs for off-label purposes;

(m) Defendants' misrepresentations regarding the addictive nature of opioids, the rate of addiction, the progression of addiction (*e.g.*, coining the "pseudo-addiction" myth), and the negative effects of long-term opioid use;

(n) Defendants' misrepresentations regarding the alleged efficacy of their systems to monitor opioid prescriptions for illicit purposes, and the alleged implementation of policies and procedures to prevent diversion into unlawful channels;

(o) Whether the flood of dangerous prescription opioid drugs into illicit channels caused, and the degree to which such diversion caused, individuals to suffer crippling addiction and to then turn to heroin;

(p) Whether Defendants' acts or inactions pose a public nuisance and should be enjoined and abated;

(q) The degree to which Defendants' ongoing perpetuation of a public nuisance should be enjoined and the terms of such injunction;

(r) Whether Plaintiff and the Class have been damaged by the unlawful actions of the Defendants and the amount of damages to the Class;

(s) The appropriate remedy for Plaintiff and the Class; and

(t) Whether, and in what amount, Plaintiff and the Class are entitled to recover court costs and attorneys' fees.

V. FACTUAL BACKGROUND

A. The History of Opioids

96. The synthetic opioids manufactured and distributed by Defendants are related to the opium poppy, which has been used to relieve pain for centuries.

97. The opium poppy was a well-known symbol of the Roman Civilization, which signified both sleep and death. The Romans used opium not only as a medicine but also as a poison.

98. During the Civil War, opioids, then known as "tinctures of laudanum," gained

popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain on the battlefield. They were also used in a wide variety of commercial products ranging from pain elixirs to cough suppressants to beverages.

99. Since 1970, opioids have been regulated under the Controlled Substances Act ("CSA"). Controlled substances are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I the highest. The CSA and Kentucky law impose a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally have been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence; Schedule III drugs are deemed to have a lower potential for abuse, but their abuse may lead to moderate or low physical dependence or high psychological dependence. 21 U.S.C. § 812; KRS 218A.060; KRS 218A.080.

100. The effects of opioids vary by duration. Long-acting opioids, such as Purdue's OxyContin and MS Contin, Janssen's Nucynta ER and Duragesic, Endo's Opana ER, and Actavis's Kadian, are designed to be taken once or twice daily and are purported to provide continuous opioid therapy for, in general, 12 hours. Short-acting opioids, such as Cephalon's Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address "episodic pain" (also referred to as "breakthrough pain") and provide fast-acting, supplemental opioid therapy lasting approximately 4 to 6 hours. Still other short-term opioids, such as Insys's Subsys, are designed to be taken in addition to long-acting opioids to specifically address breakthrough cancer pain, excruciating pain suffered by some patients with end-stage cancer. The Marketing Defendants promoted the idea that pain should be treated by taking long-acting opioids continuously and supplementing them by also taking short-acting, rapid-onset opioids for episodic

or “breakthrough” pain.

101. Patients develop tolerance to the analgesic effect of opioids relatively quickly. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same perceived level of pain reduction. The same is true of the euphoric effects of opioids—the “high.” However, opioids depress respiration, and at very high doses can and often do arrest respiration altogether. At higher doses, the effects of withdrawal are more severe. Long-term opioid use can also cause hyperalgesia, a heightened sensitivity to pain.

102. Discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for months after a complete withdrawal from opioids, depending on how long the opioids were used.

103. Opioids provide effective treatment for short-term, post-surgical and trauma-related pain, and for palliative end-of-life care. They are approved by the FDA for use in the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days. Defendants, however, have manufactured, promoted, marketed, and distributed opioids for the management of chronic pain by misleading consumers and medical providers, such as hospitals and health departments, through misrepresentations or omissions regarding the appropriate uses, risks, and safety of opioids.

104. As one doctor put it, the widespread, long-term use of opioids “was an experiment on the population of the United States. It wasn’t randomized, it wasn’t controlled, and no data was collected until they started gathering death statistics.”

B. The Opioid Epidemic

105. Prescription opioids have become widely prescribed. In 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.[15]

106. Despite the enormous number of prescriptions, recent studies have concluded that treatment with opioids is not superior to treatment with non-opioid medications for improving pain-related function.[16] Even for patients presenting to the emergency room with acute extremity pain, there is no significant or clinically important difference in pain reduction at 2 hours among single-dose treatment with ibuprofen and acetaminophen or with three different opioid and acetaminophen combination analgesics.[17]

107. In 2011, the U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention, declared prescription painkiller overdoses at epidemic levels. The News Release noted:

a. The death toll from overdoses of prescription painkillers has more than tripled in the past decade.

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[15] Katherine M. Keyes at al., *Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States*, 104 Am. J. Pub. Health e52-e59 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3935688/.

[16] Erin E. Krebs, M.D., et al., *Effect of Opioid vs Nonopioid Medications on Pain-Related Function in Patients with Chronic Back Pain or Hip or Knee Osteoarthritis Pain*, 319 JAMA 872-882 (2018), doi: 10.1001/jama.2018.0899, https://jamanetwork.com/journals/jama/article-abstract/2673971?redirect=true.

[17] Andrew K. Chang, M.D., et al., *Effect of a Single Dose of Oral Opioid and Nonopioid Analgesics on Acute Extremity Pain in the Emergency Department*, 318 JAMA 1661-1667 (2017), DOI: 10.1001/jama.2017.16190, https://jamanetwork.com/journals/jama/article-abstract/2661581?widget=personalizedcontent&previousarticle=2673971&redirect=true.

b. More than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin), and oxymorphone (Opana).

c. Overdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined.

d. The increased use of prescription painkillers for nonmedical reasons, along with growing sales, has contributed to a large number of overdoses and deaths. In 2010, 1 in every 20 people in the United States age 12 and older—a total of 12 million people—reported using prescription painkillers non-medically according to the National Survey on Drug Use and Health. Based on the data from the Drug Enforcement Administration, sales of these drugs to pharmacies and health care providers have increased by more than 300 percent since 1999.

e. Prescription drug abuse is a silent epidemic that is stealing thousands of lives and tearing apart communities and families across America.

f. Almost 5,500 people start to misuse prescription painkillers every day.[18]

108. The CDC has also identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. People who are addicted to prescription opioid painkillers – which, at the molecular level and in their effect, closely resemble heroin - are forty times more likely to be addicted to heroin.[19] According to a recent study, among young urban heroin users,

[18] *See* Press Release, Centers for Disease Control and Prevention, Prescription Painkiller Overdoses at Epidemic Levels (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.
[19] *See* Centers for Disease Control and Prevention, *Today's Heroin Epidemic*, https://www.cdc.gov/vitalsigns/heroin/index.html (last accessed August 1, 2018).

86% used opioid pain relievers prior to using heroin.[20]

109. The synthetic opioid fentanyl has been a driving force behind the nation's opioid epidemic, killing tens of thousands of Americans in overdoses. The drug is so powerful that it is now being used to execute prisoners on death row.[21]

110. In a November 2016 report, the DEA declared opioid prescription drugs, heroin, and fentanyl as the most significant drug-related threats to the United States.[22]

111. The U.S. opioid epidemic is continuing, and drug overdose deaths nearly tripled during 1999–2014. Among the 47,055 drug overdose deaths that occurred in 2014 in the United States, 28,647 (60.9%) involved an opioid.[23]

112. The rate of death from opioid overdose has quadrupled during the past 15 years in the United States. Nonfatal opioid overdoses that require medical care in a hospital or emergency department have increased by a factor of six in the past 15 years.[24]

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[20] Nat'l Inst. on Drug Abuse, *Prescription Opioids and Heroin* (Jan. 2018), https://d14rmgtrwzf5a.cloudfront.net/sites/default/files/19774-prescription-opioids-and-heroin.pdf.

[21] Smith, Mitch. *Fentanyl Used to Execute Nebraska Inmate, in First for U.S.,* (Aug. 14, 2018), https://www.nytimes.com/2018/08/14/us/carey-dean-moore-nebraska-execution-fentanyl.html.

[22] Rudd et al., Centers for Disease Control and Prevention, *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010-2015* (Dec. 30, 2016), Morbidity & Mortality Wkly. Rep. 2016; 65; 1445-1452, doi: http://dx.doi.org/10.15585/mmwr.mm655051e1, *available at* https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm.

[23] *See* Rudd et al., Centers for Disease Control and Prevention, *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010-2015* (Dec. 30, 2016), Morbidity & Mortality Wkly. Rep. 2016; 65; 1445-1452, DOI: http://dx.doi.org/10.15585/mmwr.mm655051e1, *available at* https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm.

[24] *See* Nora D. Volkow, M.D. & A. Thomas McLellan, M.D., *Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies*, 374 N Engl J Med 1253-1263 (2016), DOI: 10.1056/NEJMra1507771, http://www.nejm.org/doi/full/10.1056/NEJMra1507771, (hereinafter "Volkow & McLellan").

113. The National Institute on Drug Abuse identifies misuse and addiction to opioids as "a serious national crisis that affects public health as well as social and economic welfare."[25] The economic burden of prescription opioid misuse alone is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.[26]

114. In 2016, the President of the United States officially declared an opioid and heroin epidemic.[27]

C. The Opioid Epidemic in Kentucky

115. Kentucky has been especially ravaged by the national opioid epidemic.

116. Kentucky has an opioid prescription rate of 128.4 per 100 persons, which ranks fourth in the country (U.S. median rate: 82.5) and a benzodiazepine prescription rate of 57.4 per 100 persons which ranks fifth nationally (U.S. median rate: 37.6).[28]

117. As reported by the Centers for Disease Control, Kentucky's drug overdose rate has increased more rapidly and have remained significantly higher than the national average.

118. According to the Kentucky Office of Drug Control Policy, fatal overdoses in

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[25] *Id.*

[26] *Id.* (citing at note 2, Florence CS, et al., *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013* (Oct. 2016), 54 Med. Care 901-906 (2016), DOI: 10.1097/MLR.0000000000000625, *available at* https://www.ncbi.nlm.nih.gov/pubmed/27623005.

[27] *See* Proclamation No. 9499, 81 Fed. Reg. 65173 (Sept. 16, 2016) (proclaiming "Prescription Opioid and Heroin Epidemic Awareness Week"), *available at* https://www.gpo.gov/fdsys/pkg/FR-2016-09-22/pdf/2016-22960.pdf.

[28] *See* Leonard J. Paulozzi, M.D., *et al., Vital Signs: Variation Among States in Prescribing of Opioid Pain Relievers and Benzodiazepines – United States, 2012*, Morbidity and Mortality Weekly Report, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services (July 4, 2014). The combination of hydrocodone, oxycodone, and benzodiazepines is referred to as the "holy trinity" and significantly increases the risk of harm to those that abuse prescription pills.

Kentucky soared to unprecedented levels in 2016, jumping 7.4 percent to 1,404 overdose deaths.[29] In 2015, Kentucky overdose deaths rose by 21.1 percent over the number overdose deaths in 2014.[30]

119. According to Becker's Hospital Review, in 2017, Kentucky ranked as having the 8th highest fatal opioid overdose rate in the nation—27.9 opioid overdose deaths per every 100,000 individuals. The 2017 fatal opioid overdose rate in the United States as a whole was 14.9 opioid overdose deaths per every 100,000 individuals.[31]

120. According to data kept by KVC Kentucky, a behavioral health and child welfare organization in Lexington, the number of children in foster care in Kentucky rose from 6,000 in 2012 to 8,000 in 2015, with about a third of them entering the system because of their parents' substance abuse.[32] Children with parents addicted to drugs tend to stay in foster care longer, and they often enter the system having experienced significant trauma, which makes their care more expensive.[33]

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[29] Commonwealth of Kentucky, Justice & Public Safety Cabinet, Kentucky Office of Drug Policy 2016 Overdose Fatality Report, https://odcp.ky.gov/Reports/2016%20ODCP%20Overdose%20Fatality%20Report%20Final.pdf (last visited September 25, 2017).

[30] Drug Overdose Death Data, CDC, available at https://www.cdc.gov/drugoverdose/data/statedeaths.html (last visited September 25, 2017).

[31] Becker's Hospital Review, *50 States ranked by opioid overdose death rates* (Jan. 17, 2019), available at https://www.beckershospitalreview.com/opioids/50-states-ranked-by-opioid-overdose-death-rates.html.

[32] Shefali Luthra, Opioid crisis strains foster care system; programs aim to keep kids with mom, Kaiser Health News (August 20, 2017), available at http://www.pbs.org/newshour/rundown/opioid-crisis-strains-foster-care-system-programs-aim-keep-kids-mom/, last visited September 25, 2017. *See also* Debroah Yetter, Louisville Courier-Journal, More Ky kids being removed for abuse or neglect, (June 17, 2015), available at http://www.courier-journal.com/story/news/local/2015/06/16/ky-kids-removed-abuse-neglect/28822673/.

[33] Trista Thurston, Drug addiction drives spike in Ohio foster care, Newark Advocate (Mar. 23, 2017), available at http://www.newarkadvocate.com/story/news/crime/high-in-ohio/2017/03/23/drug-addiction-drives-spike-ohio-foster-care/99545804/.

121. In 2016, three in ten Kentuckians (27%) said they knew someone with problems from prescription painkillers.[34]

122. In Kentucky, data from hospital discharge records indicate the number of newborns with Neonatal Abstinence Syndrome, collection of symptoms newborn babies experience in withdrawing from opioid medications taken by the mother, has increased 23-fold in the last decade.[35]

123. While overall inpatient admissions for substance use treatment in Kentucky in 2015 (19,005) were down from 2005 (22,705), heroin and other opioids accounted for nearly half (46.2 percent) of those admissions in 2015, compared to just 11.6 percent in 2005.[36]

124. Data maintained by the Agency for Healthcare Research and Quality for 2007 through 2016 document a sharp increase in opioid-related inpatient hospital stays in Kentucky.

125. The rate of opioid related Emergency Department visits increased 65.6% in Kentucky between 2009 and 2014.[37]

D. <u>The Opioid Epidemic in the Kentucky River District Health Department</u>

126. Plaintiff brings this civil action to eliminate the hazard to public health and safety caused by the opioid epidemic, to abate the nuisance caused thereby, and to recoup monies that

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[34] 2016 Kentucky Health Issues Poll, released May 2017, available at: https://www.healthy-ky.org/res/images/resources/KHIP-drug-use-FINAL.pdf (last visited September 25, 2017).
[35] Kentucky Department for Public Health Division of Maternal and Child Health, 2015 Annual Report From the Public Health Neonatal Abstinence Syndrome Reporting Registry, available at:http://chfs.ky.gov/NR/rdonlyres/40B04792-10AC-490C-89D0-881ED920BAD6/0/2016AnnualMeetingPreliminaryProgram.pdf.
[36] Foundation for a Healthy Kentucky report, Substance Use and the ACA in Kentucky, available at https://www.healthy-ky.org/res/images/resources/Full-Substance-Use-Brief-Final_12_16-002-.pdf.
[37] Agency for Healthcare Research and Quality, Healthcare Cost and Utilization Project, *Statistical Brief #219, Opioid-Related Inpatient Stays and Emergency Department Visits by State, 2009-2014,* https://www.hcup-us.ahrq.gov/reports/statbriefs/sb219-Opioid-Hospital-Stays-ED-Visits-by-State.pdf

have been spent because of Defendants' false, deceptive and unfair marketing and/or unlawful diversion of prescription opioids.[38] Such economic damages were foreseeable to Defendants and were sustained because of Defendants intentional and/or unlawful actions and omissions.

127. Opioid abuse, addiction, morbidity and mortality has created a serious public health and safety crisis and is a public nuisance. The diversion of legally produced controlled substances into the illicit market causes or contributes to this public nuisance.

128. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants universally failed to comply with federal and/or state law. The Distributor Defendants are engaged in "wholesale distribution," as defined under state and federal law. Kentucky River alleges the unlawful conduct by the Distributor Defendants is responsible for the volume of prescription opioids plaguing the counties located in the Kentucky River District.[39]

129. The opioid epidemic is particularly devastating in the Kentucky River District, which is comprised of Knott, Lee, Leslie, Letcher, Owsley, Perry, and Wolfe counties.

130. From 2013 through 2017, the Kentucky River District was particularly hit hard with the opioid epidemic. Specifically, In 2017, Wolfe County had a prescription rate of 122.7 prescriptions per 100 persons, Perry County had a prescription rate of 198.7 prescriptions per 100

[38] As used herein, the term "opioid" refers to the entire family of opiate drugs including natural, synthetic and semi- synthetic opiates.

[39] *See* Laura Augner, "Needle use is through the roof' and spreading HIV. Here's what McConnell is doing", Louisville Courier Journal, August 24, 2018, https://www.courier-journal.com/story/news/2018/08/24/mcconnell-bill-aims-hiv-hepatitis-drug-infections/1073176002/.

persons, Owsley County had a prescription rate of 229.3 prescriptions per 100 persons, Knott County had a prescription rate of 229.3 prescriptions per 100 persons, Leslie County had a prescription rate of 177.5 prescriptions per 100 persons, Lee County had a prescription rate of 132.3 prescriptions per 100 persons, and Letcher County had a prescription rate of 126.7 prescriptions per 100 persons.

131. In 2016, Wolfe County had a prescription rate of 163.9 prescriptions per 100 persons, Perry County had a prescription rate of 209.3 prescriptions per 100 persons, Owsley County had a prescription rate of 251.6 prescriptions per 100 persons, Knott County had a prescription rate of 87.5 prescriptions per 100 persons, Leslie County had a prescription rate of 209.7 prescriptions per 100 persons, Lee County had a prescription rate of 147.1 prescriptions per 100 persons, and Letcher County had a prescription rate of 137.1 prescriptions per 100 persons.

132. In 2015, Wolfe County had a prescription rate of 194.9 prescriptions per 100 persons, Perry County had a prescription rate of 217.6 prescriptions per 100 persons, Owsley County had a prescription rate of 249.7 prescriptions per 100 persons, Knott County had a prescription rate of 89.7 prescriptions per 100 persons, Leslie County had a prescription rate of 217.7 prescriptions per 100 persons, Lee County had a prescription rate of 160.1 prescriptions per 100 persons, and Letcher County had a prescription rate of 150.8 prescriptions per 100 persons.

133. In 2014, Wolfe County had a prescription rate of 198.7 prescriptions per 100 persons, Perry County had a prescription rate of 243.4 prescriptions per 100 persons, Owsley County had a prescription rate of 262.2 prescriptions per 100 persons, Knott County had a prescription rate of 75.4 prescriptions per 100 persons, Leslie County had a prescription rate of 244.2 prescriptions per 100 persons, Lee County had a prescription rate of 203.8 prescriptions per 100 persons, and Letcher County had a prescription rate of 162.0 prescriptions per 100 persons.

134. In 2013, Wolfe County had a prescription rate of 184.5 prescriptions per 100 persons, Perry County had a prescription rate of 246.2 prescriptions per 100 persons, Owsley County had a prescription rate of 272.6 prescriptions per 100 persons, Knott County had a prescription rate of 78.3 prescriptions per 100 persons, Leslie County had a prescription rate of 238.2 prescriptions per 100 persons, Lee County had a prescription rate of 202.3 prescriptions per 100 persons, and Letcher County had a prescription rate of 160.6 prescriptions per 100 persons. As a direct and proximate result of Defendants' conduct, Kentucky River has suffered actual injury and damages including, but not limited to, significant increased expenses for providing public health services, including but not limited to: (1) providing vaccinations and public health services related to public outbreaks of HIV, Hepatitis A, B, and C; (2) administering and operating needle exchange programs; (3) providing public safety relating to the opioid epidemic; (4) providing public health educational programs on preventing opioid addiction, abuse, and/or dependency; (5) providing prenatal services to infants and mothers with opioid-related medical conditions; (6) providing services for at least the first two years of a child's life, to children born with opioid-related medical conditions and children whose families suffer from opioid-related disabilities or incapacitation; and (7) providing services for at least the first two years of a child's life, to mothers and families of children suffering from opioid-related medical conditions. While Kentucky River normally has some expenses related to these services, the expenses have been significantly increased as a direct and proximate result of Defendants' conduct, and thus constitute specific and special injuries. The increased expenditures have been a necessary means to respond to issues created by unlawful opioid prescription drugs in the Kentucky River District, but much greater expenditures are needed to abate the serious problems caused by the opioid epidemic.

135. Kentucky River's costs associated with public safety relating to the opioid epidemic

including but are not limited to the following: costs associated with public outbreaks of HIV and Hepatitis A, B and C; costs associated with the operation of needle-exchange programs; costs associated with educational programs aimed at teaching the public about the potential dangers associated with opioid use, including but not limited to opioid addiction, abuse, and/or dependency; costs associated with educational programs aimed at minimizing opioid addiction, abuse, and/or dependency; costs associated with educational programs aimed at teaching the public about alternative treatments to opioids; costs for providing prenatal services to infants and mothers with opioid-related medical conditions; costs for providing services for at least the first two years of a child's life, to children born with opioid-related medical conditions and children whose families suffer from opioid-related disabilities or incapacitation; and costs for providing services for at least the first two years of a child's life, to mothers and families of children suffering from opioid-related medical conditions.

E. Congressional Response to Opioid Crisis

136. Congressional interest in the opioid crisis has been intense. During the current congressional term, multiple committees in both the House and Senate have conducted dozens of hearings exploring the issue from almost every angle, including effects on the health care system, people and their communities, law enforcement, workplaces, schools, and the Native American community. Congressional efforts culminated in the passage of the "Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act," or the "SUPPORT for Patients and Communities Act." This Bill passed the House by a vote of 396-14 on June 22, 2018, passed the Senate by a vote of 99-1 on September 17, 2018, and was signed into law by the President on October 24, 2018. Among other provisions, the Bill made it easier to intercept drugs being shipped into the country, authorized new funding for more comprehensive

treatment, sped up research on non-addictive painkillers, and provided for broader coverage for substance abuse under Medicare and Medicaid regulations that have occasionally stood in the way of treatment.

F. Defendants' False, Deceptive, and Unfair Marketing of Opioids

137. The opioid epidemic did not happen by accident.

138. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

139. Each Marketing Defendant has conducted, and continues to conduct, a marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain, resulting in opioid treatment for a far broader group of patients who are much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. In connection with this scheme, each Marketing Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny, trivialize, or materially understate the risks of opioids while overstating the benefits of using them for chronic pain.

140. The Marketing Defendants have disseminated these common messages to reverse the generally accepted medical understanding of opioids and risks of opioid use. They disseminated these messages directly, through their sales representatives, in speaker groups led by

physicians that the Marketing Defendants recruited for their support of their marketing messages, and through unbranded marketing and industry-funded Front Groups.

141. The Marketing Defendants' efforts have been wildly successful. Opioids are now the most prescribed class of drugs. Globally, opioid sales generated $11 billion in revenue for drug companies in 2010 alone; sales in the United States have exceeded $8 billion in revenue annually since 2009.[40] In an open letter to the nation's physicians in August 2016, the then U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors ... [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."[41] This epidemic has resulted in a flood of prescription opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or obtain opioids from licensed dispensaries, they often turn to the street to buy prescription opioids or even non-prescription opioids, like heroin.

142. The Marketing Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

143. As alleged throughout this Complaint, Defendants' conduct created a public health crisis and a public nuisance.

144. The public nuisance—i.e., the opioid epidemic—created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm can be abated by,

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[40] *See* Katherine Eban, *Oxycontin: Purdue Pharma's Painful Medicine*, FORTUNE (Nov. 9, 2011), http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/; David Crow, *Drugmakers Hooked on $10bn Opioid Habit*, FINANCIAL TIMES (Aug. 10, 2016).

[41] Letter from Vivek H. Murthy, M.D., U.S. Surgeon General, *supra* n.15.

inter alia, (a) educating prescribers (especially primary care physicians and the most prolific prescribers of opioids) and patients regarding the true risks and benefits of opioids, including the risk of addiction, in order to prevent the next cycle of addiction; (b) providing addiction treatment to patients who are already addicted to opioids; and (c) making naloxone widely available so that overdoses are less frequently fatal.

145. Defendants have the ability to act to abate the public nuisance, and the law recognizes that they must do so. It is the manufacturer of a drug that has primary responsibility to ensure the safety, efficacy, and appropriateness of a drug's labeling, marketing, and promotion. All companies in the supply chain of a controlled substance are primarily responsible for ensuring that such drugs are only distributed and dispensed to appropriate patients and not diverted. These responsibilities, to ensure that their products and practices meet both federal and state consumer protection laws and regulations, exist independent of any FDA or DEA regulation. As registered manufacturers and distributors of controlled substances, Defendants are placed in a position of special trust and responsibility, and are uniquely positioned, based on their knowledge of prescribers and orders, to act as a first line of defense.

G. Each Marketing Defendant Used Multiple Avenues to Disseminate Their False and Deceptive Statements About Opioids.

146. The Marketing Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients throughout the United States. The Marketing Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout the Commonwealth and Plaintiffs' communities.

147. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by the drug manufacturers' corporate headquarters. This

comprehensive approach ensures that the Marketing Defendants' messages are accurately and consistently delivered across marketing channels – including detailing visits, speaker events, and advertising – and in each sales territory. The Marketing Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

148. The Marketing Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons (the company employees who respond to physician inquiries); centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. The Marketing Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.

1. Direct Marketing

149. The Marketing Defendants' misrepresentations fall into the following nine categories: The risk of addiction from chronic opioid therapy is low; To the extent there is a risk of addiction, it can be easily identified and managed; Signs of addictive behavior are "pseudoaddiction," requiring more opioids; Opioid withdrawal can be avoided by tapering; Opioid doses can be increased without limit or greater risks; Long-term opioid use improves functioning; Alternative forms of pain relief pose greater risks than opioids; A version of OxyContin marketed by Purdue was effective in providing 12-hour pain relief; and New formulations of certain opioids successfully deter abuse.

150. Each of these propositions was false. The Marketing Defendants knew this, but they nonetheless set out to convince physicians, patients, and the public at large of the truth of each of these propositions in order to expand the market for their opioids.

151. The categories of misrepresentations are offered to organize the numerous statements the Marketing Defendants made and to explain their role in the overall marketing effort, not as a checklist for assessing each Marketing Defendant's liability. While each Marketing Defendant deceptively promoted their opioids specifically, and, together with other Marketing Defendants, opioids generally, not every Marketing Defendant propagated (or needed to propagate) each misrepresentation. Each Marketing Defendant's conduct, and each misrepresentation, contributed to an overall narrative that aimed to—and did—mislead doctors, patients, and payors about the risks and benefits of opioids. While this Complaint endeavors to document examples of each Marketing Defendant's misrepresentations and the manner in which they were disseminated, they are just that—examples. The Complaint is not, especially prior to discovery, an exhaustive catalog of the nature and manner of each deceptive statement by each Marketing Defendant.

a. Falsehood #1: The Risk of Addiction from Chronic Opioid Therapy is Low

152. Central to the Marketing Defendants' promotional scheme was the misrepresentation that opioids are rarely addictive when taken for chronic pain. Through their marketing efforts, the Marketing Defendants advanced the idea that the risk of addiction is low when opioids are taken as prescribed by "legitimate" pain patients. That, in turn, directly led to the expected and intended result that doctors prescribed more opioids to more patients—thereby enriching the Marketing Defendants and substantially contributing to the opioid epidemic.

153. Each of the Marketing Defendants claimed that the potential for addiction from its opioids was relatively small or non-existent, even though there was no scientific evidence to support those claims. None of them have acknowledged, retracted, or corrected their false statements.

154. In fact, studies have shown that a substantial percentage of long-term users of opioids experience addiction. Addiction can result from the use of any opioid, "even at recommended dose,"[42] and the risk substantially increases with more than three months of use.[43] As the CDC Guideline states, "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction).[44]

i. Purdue's Misrepresentations Regarding Addiction Risk

155. When it launched OxyContin, Purdue knew it would need data to overcome decades of wariness regarding opioid use. It needed some sort of research to back up its messaging. But Purdue had not conducted any studies about abuse potential or addiction risk as part of its application for FDA approval for OxyContin. Purdue (and, later, the other Defendants) found this "research" in the form of a one-paragraph letter to the editor published in the New England Journal of Medicine ("NEJM") in 1980.

156. This letter, by Dr. Hershel Jick and Jane Porter, declared the incidence of addiction "rare" for patients treated with opioids.[45] They had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. Porter and Jick considered a patient not addicted if there was no sign of addiction noted in patients' records.

157. As Dr. Jick explained to a journalist years later, he submitted the statistics to NEJM

[42] FDA announces safety labeling changes and post market study requirements for extended-release and long-acting opioid analgesics, FDA (Sept. 10, 2013). *See also* FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death, FDA (Mar. 22, 2016).
[43] CDC Guideline at 21.
[44] *Id.* at 2.
[45] Jane Porter and Herschel Jick, MD, *Addiction Rare in Patients Treated with Narcotics*, 302(2) N Engl J Med. 123 (Jan. 10, 1980), http://www.nejm.org/doi/pdf/10.1056/NEJM198001103020221.

as a letter because the data were not robust enough to be published as a study.[46]

158. Purdue nonetheless began repeatedly citing this letter in promotional and educational materials as evidence of the low risk of addiction, while failing to disclose that its source was a letter to the editor, not a peer-reviewed paper.[47] Citation of the letter, which was largely ignored for more than a decade, significantly increased after the introduction of OxyContin. While first Purdue and then other Marketing Defendants used it to assert that their opioids were not addictive, "that's not in any shape or form what we suggested in our letter," according to Dr. Jick.

159. In 1996, Defendant Purdue made a deal with Pharmaceutical giant, Abbott Laboratories, under which Abbott's sales force would promote Purdue's lead opioid, OxyContin, in hospitals.[48]

160. Purdue specifically used the Porter and Jick letter in its 1998 promotional video "I got my life back," in which Dr. Alan Spanos states "In fact, the rate of addiction amongst pain patients who are treated by doctors *is much less than 1%.*"[49] Purdue trained its sales representatives to tell prescribers that less than 1% of patients who took OxyContin became addicted. (In 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate

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[46] Barry Meier, *Pain Killer: A "Wonder" Drug's Trail Of Addiction And Death,* 174 (Rodale 2003) (herein after "Pain Killer").

[47] J. Porter & H. Jick, Addiction Rare in Patients Treated with Narcotics, 302(2) New. Eng. J. Med. 123 (1980).

[48] "Abbott and Purdue consciously targeted hospitals. [Purdue] representatives will work with their Abbott counterparts to make calls on all Pharmacy and Therapeutic (P&T) communities." "[S]ales force will provide the *appropriate* clinical data necessary to continue to add OxyContin Tablets to hospital formularies." 2002 Purdue Budget Plan, https://khn.org/news/purdue-and-the-oxycontin-files/ (last visited Aug. 20, 2018) (emphasis added).

[49] Our Amazing World, *Purdue Pharma OxyContin Commercial*, https://www.youtube.com/watch?v=Er78Dj5hyeI, (last accessed August 1, 2018) (emphasis added).

was 13%.)[50]

161. Other Defendants relied on and disseminated the same false and deceptive messaging. The enormous impact of Defendants' misleading amplification of this letter was well documented in another letter published in the NEJM on June 1, 2017, describing the way the one-paragraph 1980 letter had been irresponsibly cited and, in some cases, "grossly misrepresented." In particular, the authors of this letter explained:

162. [W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy.[51]

163. "It's difficult to overstate the role of this letter," said Dr. David Juurlink of the University of Toronto, who led the analysis. "It was the key bit of literature that helped the opiate manufacturers convince front-line doctors that addiction is not a concern."[52]

164. Alongside its use of the Porter and Jick letter, Purdue also crafted its own materials and spread its deceptive message through numerous additional channels. In its 1996 press release

[50] Keefe, *Empire of Pain*.
[51] Pamela T.M. Leung, B.Sc. Pharm., Erin M. Macdonald, M.Sc., Matthew B. Stanbrook, M.D., Ph.D., Irfan Al Dhalla, M.D., David N. Juurlink, M.D., Ph.D., *A 1980 Letter on the Risk of Opioid Addiction*, 376 N Engl. J Med 2194-95 (June 1, 2017), http://www.nejm.org/doi/full/10.1056/NEJMc1700150#t=article.
[52] *Painful words: How a 1980 letter fueled the opioid epidemic*, STAT (May 31, 2017), https://www.statnews.com/2017/05/31/opioid-epidemic-nejm-letter/.

announcing the release of OxyContin, for example, Purdue declared, "The fear of addiction is exaggerated."[53]

165. At a hearing before the House of Representatives' Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce in August 2001, Purdue emphasized "legitimate" treatment, dismissing cases of overdose and death as something that would not befall "legitimate" patients: "Virtually all of these reports involve people who are abusing the medication, not patients with legitimate medical needs under the treatment of a healthcare professional."[54]

166. Purdue spun this baseless "legitimate use" distinction out even further in a patient brochure about OxyContin, called *A Guide to Your New Pain Medicine and How to Become a Partner Against Pain.* In response to the question "Aren't opioid pain medications like OxyContin Tablets 'addicting'?" Purdue claimed that there was no need to worry about addiction if taking opioids for legitimate, "medical" purposes: "Drug addiction means using a drug to get "high" rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful."

167. Sales representatives marketed OxyContin as a product "to start with and to stay with."[55] Sales representatives also received training in overcoming doctors' concerns about addiction with talking points they knew to be untrue about the drug's abuse potential. One of

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[53] Press Release, OxyContin, *New Hope for Millions of Americans Suffering from Persistent Pain: Long-Acting OxyContin Tablets Now Available to Relieve Pain* (May 31, 1996, 3:47pm), http://documents.latimes.com/oxycontin-press-release-1996/.

[54] *Oxycontin: Its Use and Abuse: Hearing Before the H. Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce*, 107th Cong. 1 (Aug. 28, 2001) (statement of Michael Friedman, Executive Vice President, Chief Operating Officer, Purdue Pharma, L.P.), https://www.gpo.gov/fdsys/pkg/CHRG-107hhrg75754/html/CHRG-107hhrg75754.htm.

[55] Keefe, *Empire Of Pain.*

Purdue's early training memos compared doctor visits to "firing at a target," declaring that "[a]s you prepare to fire your 'message,' you need to know where to aim and what you want to hit!"[56] According to the memo, the target is physician resistance based on concern about addiction: "The physician wants pain relief for these patients without addicting them to an opioid."[57]

168. Purdue, through its unbranded website *Partners Against Pain*,[58] stated the following: "Current Myth: Opioid addiction (psychological dependence) is an important clinical problem in patients with moderate to severe pain treated with opioids. Fact: Fears about psychological dependence are exaggerated when treating appropriate pain patients with opioids."

169. Former sales representative Steven May, who worked for Purdue from 1999 to 2005, explained to a journalist how he and his coworkers were trained to overcome doctors' objections to prescribing opioids. The most common objection he heard about prescribing OxyContin was that "it's just too addictive."[59] May and his coworkers were trained to "refocus" doctors on "legitimate" pain patients, and to represent that "legitimate" patients would not become addicted. In addition, they were trained to say that the 12-hour dosing made the extended-release opioids less "habit-forming" than painkillers that need to be taken every four hours.

170. According to interviews with prescribers and former Purdue sales representatives,

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[56] *Pain Killer, supra* n. 63, at 102.
[57] *Id.*
[58] *Partners Against Pain* consists of both a website, styled as an "advocacy community" for better pain care, and a set of medical education resources distributed to prescribers by sales representatives. It has existed since at least the early 2000s and has been a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. One early pamphlet, for example, answered concerns about OxyContin's addictiveness by claiming: "Drug addiction means using a drug to get 'high' rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful."
[59] David Remnick, *How OxyContin Was Sold to the Masses* (Steven May interview with Patrick Radden Keefe), The New Yorker (Oct. 27, 2017), https://www.newyorker.com/podcast/the-new- yorker-radio-hour/how-oxycontin-was-sold-to-the-masses.

Purdue has continued to distort or omit the risk of addiction while failing to correct its earlier misrepresentations, leaving many doctors with the false impression that pain patients will only rarely become addicted to opioids.

171. With regard to addiction, Purdue's label for OxyContin has not sufficiently disclosed the true risks to, and experience of, its patients. Until 2014, the OxyContin label stated in a black-box warning that opioids have "abuse potential" and that the "risk of abuse is increased in patients with a personal or family history of substance abuse."

172. However, the FDA made clear to Purdue as early as 2001 that the disclosures in its OxyContin label were insufficient.

173. In 2001, Purdue revised the indication and warnings for OxyContin.

174. In the end, Purdue narrowed the recommended use of OxyContin to situations when "a continuous, around-the-clock analgesic is needed for an extended period of time" and added a warning that "[t]aking broken, chewed, or crushed OxyContin tablets" could lead to a "potentially fatal dose." However, Purdue did not, until 2014, change the label to indicate that OxyContin should not be the first therapy, or even the first opioid, used, and did not disclose the incidence or risk of overdose and death even when OxyContin was not abused. Purdue announced the label changes in a letter to health care providers.

ii. Endo's Misrepresentations Regarding Addiction Risk

175. Endo also falsely represented that addiction is rare in patients who are prescribed opioids.

176. Until April 2012, Endo's website for Opana, www.opana.com, stated that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted."

177. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that Endo improperly instructed its sales representatives to diminish and distort the risk of addiction associated with Opana ER.

178. One of the Front Groups with which Endo worked most closely was the American Pain Foundation ("APF"), described more fully below.

179. APF conveyed through its National Initiative on Pain Control ("NIPC") and its website www.*Painknowledge.com*, which claimed that "[p]eople who take opioids as prescribed usually do not become addicted."

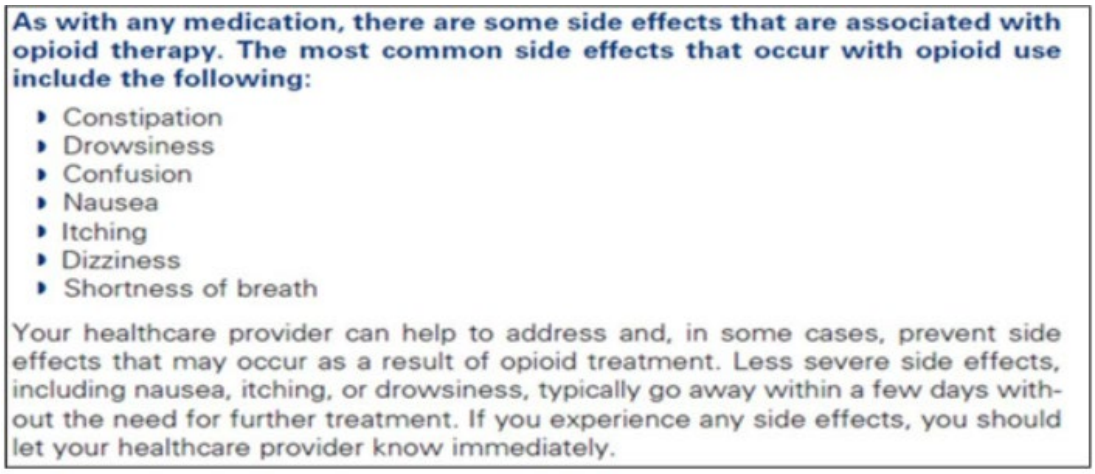
180. Another Endo website, www.*PainAction.com*, stated: "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

181. A brochure available on www.*Painknowledge.com* titled "*Pain: Opioid Facts*," an Endo- sponsored NIPC, stated that "people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted." In numerous patient education pamphlets, Endo repeated this deceptive message.

182. In a patient education pamphlet titled "*Understanding Your Pain: Taking Oral Opioid Analgesics*," Endo answers the hypothetical patient question— "What should I know about opioids and addiction?"—by focusing on explaining what addiction is ("a chronic brain disease") and is not ("Taking opioids for pain relief"). It goes on to explain that "[a]ddicts take opioids for other reasons, such as unbearable emotional problems. Taking opioids as prescribed for pain relief is not addiction." This publication is still available online and was edited by KOL Dr. Russell

Portenoy.[60]

183. In addition, a 2009 patient education publication, *Pain: Opioid Therapy*, funded by Endo and posted on www.*Painknowledge.com*, omitted addiction from the "common risks" of opioids, as shown below:



As with any medication, there are some side effects that are associated with opioid therapy. The most common side effects that occur with opioid use include the following:

- Constipation
- Drowsiness
- Confusion
- Nausea
- Itching
- Dizziness
- Shortness of breath

Your healthcare provider can help to address and, in some cases, prevent side effects that may occur as a result of opioid treatment. Less severe side effects, including nausea, itching, or drowsiness, typically go away within a few days without the need for further treatment. If you experience any side effects, you should let your healthcare provider know immediately.

iii. Janssen's Misrepresentations Regarding Addiction Risk

184. Janssen likewise misrepresented the addiction risk of opioids on its websites and print materials. One website, *Let's Talk Pain*, states, among other things, that "the stigma of drug addiction and abuse" associated with the use of opioids stemmed from a "lack of understanding addiction."

185. The *Let's Talk Pain* website also perpetuated the concept of pseudoaddiction, associating patient behaviors such as "drug seeking," "clock watching," and "even illicit drug use or deception" with undertreated pain which can be resolved with "effective pain management."

186. A Janssen unbranded website, www.*PrescribeResponsibly.com*, states that concerns about opioid addiction are "overestimated" and that "true addiction occurs only in a small

[60] Margo McCaffery, RN MS, FAAN and Chris Pasero, RN, MS FAAN, *Understanding Your Pain, Taking Oral Opioid Analgesics*, available at http://www.thblack.com/links/rsd/understand_pain_opioid_analgesics.pdf (last accessed October 26, 2018).

percentage of patients."[61]

187. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults*, which, as seen below, described as "myth" that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain" (emphasis in original). Until recently, this guide was still available online.

188. Janssen's website for Duragesic included a section addressing "Your Right to Pain Relief" and a hypothetical patient's fear that "I'm afraid I'll become a drug addict." The website's response: "Addiction is relatively rare when patients take opioids appropriately."

iv. Cephalon's Misrepresentations Regarding Addiction Risk

189. Cephalon sponsored and facilitated the development of a guidebook, *Opioid Medications and REMS: A Patient's Guide*, which included claims that "patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids." Similarly, Cephalon sponsored APF's *Treatment Options*: *A Guide for People Living with Pain* (2007), which

[61] Keith Candiotti, M.D., *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, http://www.prescriberesponsibly.com/articles/opioid-pain-management (last modified July 2, 2015).

taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.

190. For example, a 2003 Cephalon-sponsored CME presentation titled *Pharmacologic Management of Breakthrough or Incident Pain*, posted on Medscape in February 2003, teaches:

191. [C]hronic pain is often undertreated, particularly in the non-cancer patient population.... The continued stigmatization of opioids and their prescription, coupled with often unfounded and self-imposed physician fear of dealing with the highly regulated distribution system for opioid analgesics, remains a barrier to effective pain management and must be addressed. Clinicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse. In fact, patient fears of developing substance abuse behaviors such as addiction often lead to under treatment of pain. The concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse.[62]

v. Mallinckrodt's Misrepresentations Regarding Addiction Risk

192. As described below, Mallinckrodt promoted its branded opioids Exalgo and Xartemis XR, and opioids generally, in a campaign that consistently mischaracterized the risk of addiction. Mallinckrodt did so through its website and sales force, as well as through unbranded communications distributed through the "C.A.R.E.S. Alliance" it created and led.

193. Mallinckrodt in 2010 created the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as "a coalition of national patient

[62] Michael J. Brennan, et al., Pharmacologic Management of Breakthrough or Incident Pain, Medscape, http://www.medscape.org/viewarticle/449803, (last accessed July 27, 2017).

safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing responsible prescribing habits." The "C.A.R.E.S. Alliance" itself is a service mark of Mallinckrodt LLC (and was previously a service mark of Mallinckrodt, Inc.) copyrighted and registered as a trademark by Covidien, its former parent company. Materials distributed by the C.A.R.E.S. Alliance, however, include unbranded publications that do not disclose a link to Mallinckrodt.

194. By 2012, Mallinckrodt, through the C.A.R.E.S. Alliance, was promoting a book titled *Defeat Chronic Pain Now!* This book is still available online. The false claims and misrepresentations in this book include the following statements:

a. "Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."

b. "It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy."

c. "When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving."

d. "Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."

e. "**The bottom line:** Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."

f. "Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."

g. "Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction."

195. In a 2013 *Mallinckrodt Pharmaceuticals Policy Statement Regarding the Treatment of Pain and Control of Opioid Abuse*, which is still available online, Mallinckrodt stated that, "[s]adly, even today, pain frequently remains undiagnosed and either untreated or undertreated" and cites to a report that concludes that "the majority of people with pain use their prescription drugs properly, are not a source of misuse, and should not be stigmatized or denied access because of the misdeeds or carelessness of others."

196. Marketing Defendants' suggestions that the opioid epidemic is the result of bad patients who manipulate doctors to obtain opioids illicitly helped further their marketing scheme is at odds with the facts. While there are certainly patients who unlawfully obtain opioids, they are a small minority. For example, patients who "doctor-shop"—i.e., visit multiple prescribers to obtain opioid prescriptions—are responsible for roughly 2% of opioid prescriptions. The epidemic of opioid addiction and abuse is overwhelmingly a problem of false marketing (and unconstrained distribution) of the drugs, not problem patients.

b. Falsehood #2: To The Extent There is a Risk of Addiction, It Can Be Easily Identified and Managed

197. While continuing to maintain that most patients can safely take opioids long-term for chronic pain without becoming addicted, the Marketing Defendants assert that to the extent that *some* patients are at risk of opioid addiction, doctors can effectively identify and manage that

risk by using screening tools or questionnaires. In materials they produced, sponsored, or controlled, Defendants instructed patients and prescribers that screening tools can identify patients predisposed to addiction, thus making doctors feel more comfortable prescribing opioids to their patients and patients more comfortable starting opioid therapy for chronic pain. These tools, they say, identify those with higher addiction risks (stemming from personal or family histories of substance use, mental illness, trauma, or abuse) so that doctors can then more closely monitor those patients.

198. Purdue shared its *Partners Against Pain* "Pain Management Kit," which contains several screening tools and catalogues of Purdue materials.

199. Janssen, on its website www.*PrescribeResponsibly.com*, states that the risk of opioid addiction "can usually be managed" through tools such as opioid agreements between patients and doctors.[63] The website, which directly provides screening tools to prescribers for risk assessments,[64] includes a "[f]our question screener" to purportedly help physicians identify and address possible opioid misuse.[65]

200. Purdue and Cephalon sponsored the APF's *Treatment Options: A Guide for People Living with Pain* (2007), which also falsely reassured patients that opioid agreements between doctors and patients can "ensure that you take the opioid as prescribed" and counseled patients that opioids "give [pain patients] a quality of life we deserve."

201. Purdue sponsored a 2011 webinar taught by Dr. Lynn Webster, entitled *Managing*

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[63] Howard A. Heit, MD, FACP, FASAM and Douglas L. Gourlay, MD, MSc, FRCPC, FASAM, *What a Prescriber Should Know Before Writing the First Prescription*, Prescribe Responsibly, http://www.prescriberesponsibly.com/articles/before-prescribing-opioids#pseudoaddiction, (last modified July 2, 2015).
[64] Risk Assessment Resources, http://www.prescriberesponsibly.com/risk-assessment-resources (last accessed August 1, 2018).
[65] *Id.*

Patient's Opioid Use: Balancing the Need and Risk. This publication misleadingly taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths."

202. Purdue sponsored a 2011 CME program titled *Managing Patient's Opioid Use: Balancing the Need and Risk*. This presentation deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths."

203. Purdue also funded a 2012 CME program called *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. The presentation deceptively instructed doctors that, through the use of screening tools, more frequent refills, and other techniques, even high-risk patients showing signs of addiction could be treated with opioids.

204. Endo paid for a 2007 supplement available for continuing education credit in the *Journal of Family Practice* written by a doctor who became a member of Endo's speaker's bureau in 2010. This publication, entitled *Pain Management Dilemmas in Primary Care*: *Use of Opioids*, (i) recommended screening patients using tools like (a) the *Opioid Risk Tool* (ORT) created by Dr. Webster and linked to Janssen or (b) the *Screener and Opioid Assessment for Patients with Pain*, and (ii) taught that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts. The ORT was linked to Endo-supported websites, as well.

205. There are three fundamental flaws in the Marketing Defendants' representations that doctors can consistently identify and manage the risk of addiction. First, there is no reliable scientific evidence that doctors can depend on the screening tools currently available to materially limit the risk of addiction. Second, there is no reliable scientific evidence that high-risk patients

identified through screening can take opioids long-term without triggering addiction, even with enhanced monitoring. Third, there is no reliable scientific evidence that patients who are not identified through such screening can take opioids long-term without significant danger of addiction.

c. Falsehood #3: Signs of Addictive Behavior are "Pseudoaddiction" Requiring More Opioids

206. The Marketing Defendants instructed patients and prescribers that signs of addiction are actually indications of untreated pain, such that the appropriate response is to prescribe even more opioids. Dr. David Haddox, who later became a Senior Medical Director for Purdue, published a study in 1989 coining the term "pseudoaddiction," which he characterized as "the iatrogenic syndrome of abnormal behavior developing as a direct consequence of inadequate pain management."[66] In other words, people on prescription opioids who exhibited classic signs of addiction— for example, asking for more and higher doses of opioids, self-escalating their doses, or claiming to have lost prescriptions in order to get more opioids—were not addicted, but rather simply suffering from under-treatment of their pain.

207. In the materials and outreach they produced, sponsored, or controlled, the Marketing Defendants made each of these misrepresentations and omissions, and have never acknowledged, retracted, or corrected them.

208. Cephalon, Endo, and Purdue sponsored the Federation of State Medical Boards' ("FSMB") *Responsible Opioid Prescribing* (2007) written by Dr. Scott Fishman and discussed in more detail below, which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, which are

[66] David E. Weissman and J. David Haddox, *Opioid pseudoaddiction—an iatrogenic syndrome*, 36(3) Pain 363-66 (Mar. 1989), https://www.ncbi.nlm.nih.gov/pubmed/2710565. ("Iatrogenic" describes a condition induced by medical treatment.)

signs of genuine addiction, are all really signs of "pseudoaddiction."

209. Purdue posted an unbranded pamphlet entitled *Clinical Issues in Opioid Prescribin*g on its unbranded website, www.*PartnersAgainstPain.com*, in 2005, and circulated this pamphlet through at least 2007 and on its website through at least 2013. The pamphlet listed conduct including "illicit drug use and deception" that it claimed was not evidence of true addiction but "pseudoaddiction" caused by untreated pain.

210. According to documents provided by a former Purdue detailer, sales representatives were trained and tested on the meaning of pseudoaddiction, from which it can be inferred that sales representatives were directed to, and did, describe pseudoaddiction to prescribers. Purdue's *Pain Management Kit* is another example of publication used by Purdue's sales force that endorses pseudoaddiction by claiming that "pain-relief seeking behavior can be mistaken for drug-seeking behavior." In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that the kit was in use from roughly 2011 through at least June 2016.

211. Endo also sponsored a NIPC CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction and listed "[d]ifferentiation among states of physical dependence, tolerance, pseudoaddiction, and addiction" as an element to be considered in awarding grants to CME providers.

212. Endo itself has repudiated the concept of pseudoaddiction. In finding that "[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents," the New York Attorney General, in a 2016 settlement with Endo, reported that "Endo's Vice President for Pharmacovigilance and Risk Management testified to [the NY AG] that he was not aware of any research validating the 'pseudoaddiction' concept" and

acknowledged the difficulty in distinguishing "between addiction and 'pseudoaddiction.'"[67] Endo thereafter agreed not to "use the term 'pseudoaddiction' in any training or marketing" in New York.

213. The FAQs section of www.*pain-topics.org*, a now-defunct website to which Mallinckrodt provided funding, also contained misleading information about pseudoaddiction. Specifically, the website advised providers to "keep in mind" that signs of potential drug diversion, rather than signaling "actual" addiction, "may represent pseudoaddiction," which the website described as behavior that occurs in patients when pain is "undertreated" and includes patients becoming "very focused on obtaining opioid medications and may be erroneously perceived as 'drug seeking.'"

214. Janssen sponsored, funded, and edited a website called *Let's Talk Pain*, which in 2009 stated "pseudoaddiction . . . refers to patient behaviors that may occur when pain is undertreated . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management." This website was accessible online until at least May 2012. Janssen also currently runs a website, www.*Prescriberesponsibly.com*, which claims that concerns about opioid addiction are "overestimated," and describes pseudoaddiction as "a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically, when the pain is treated appropriately the inappropriate behavior ceases."[68]

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[67] Attorney General of the State of New York, In the Matter of Endo Health Solutions Inc. & Endo Pharmaceuticals Inc., Assurance No.:15-228, Assurance of Discontinuance Under Executive Law Section 63. Subdivision 15 at 7.

[68] Howard Heit, MD, FACP, FASAM, & Douglas Gourlay, MD, MSc, FRCPC, FASAM, *What a Prescriber Should Know Before Writing the First Prescription*, Prescribe Responsibly, http://www.prescriberesponsibly.com/articles/before-prescribing-opioids, (last accessed July 16, 2018).

215. The CDC Guideline nowhere recommends attempting to provide more opioids to patients exhibiting symptoms of addiction. Dr. Lynn Webster, a KOL discussed below, admitted that pseudoaddiction "is already something we are debunking as a concept" and became "too much of an excuse to give patients more medication. It led us down a path that caused harm."

d. Falsehood #4: Opioid Withdrawal Can Be Avoided By Tapering

216. In an effort to underplay the risk and impact of addiction, the Marketing Defendants falsely claimed that, while patients become physically dependent on opioids, physical dependence is not the same as addiction and can be easily addressed, if and when pain relief is no longer desired, by gradually tapering a patient's dose to avoid the adverse effects of withdrawal. Defendants failed to disclose the extremely difficult and painful effects that patients can experience when they are removed from opioids—adverse effects that also make it less likely that patients will be able to stop using the drugs. Defendants also failed to disclose how difficult it is for patients to stop using opioids after they have used them for a prolonged period.

217. A non-credit educational program sponsored by Endo, *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, could be avoided by simply tapering a patient's opioid dose over ten days.

218. However, this claim is at odds with the experience of patients addicted to opioids. Most patients who have been taking opioids regularly will, upon stopping treatment, experience withdrawal, characterized by intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among others. This painful and arduous struggle to terminate use can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

219. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that "Symptoms of physical dependence can often be ameliorated by

gradually decreasing the dose of medication during discontinuation," but the guide did not disclose the significant hardships that often accompany cessation of use.

220. To this day, the Marketing Defendants have not corrected or retracted their misrepresentations regarding tapering as a solution to opioid withdrawal.

e. Falsehood #5: Opioid Doses Can Be Increased Without Limit or Greater Risk

221. In materials they produced, sponsored, or controlled, Marketing Defendants instructed prescribers that they could safely increase a patient's dose to achieve pain relief. Each of the Marketing Defendants' claims was deceptive in that they omitted warnings of increased adverse effects that occur at higher doses that were confirmed by scientific evidence.

222. These misrepresentations were integral to the Marketing Defendants' promotion of prescription opioids. As discussed above, patients develop a tolerance to opioids' analgesic effects, so that achieving long-term pain relief requires constantly increasing the dose.

223. In addition, sales representatives aggressively pushed doctors to prescribe stronger doses of opioids. For example, one Purdue sales representative wrote about how his regional manager would drill the sales team on their upselling tactics:

224. It went something like this. "Doctor, what is the highest dose of OxyContin you have ever prescribed?" "20mg Q12h." "Doctor, if the patient tells you their pain score is still high you can increase the dose 100% to 40mg Q12h, will you do that?" "Okay." "Doctor, what if that patient then came back and said their pain score was still high, did you know that you could increase the OxyContin dose to 80mg Q12h, would you do that?" "I don't know, maybe." "Doctor, but you do agree that you would at least Rx the 40mg dose, right?" "Yes."

225. The next week the representative would see that same doctor and go through the same discussion with the goal of selling higher and higher doses of OxyContin. Stronger doses

were more expensive and increased the likelihood of addiction.

226. These misrepresentations were particularly dangerous. Opioid doses at or above 50 MME (morphine milligram equivalents)/day double the risk of overdose compared to 20 MME/day, and 50 MME is equal to just 33 mg of oxycodone. The recommendation of 320 mg every twelve hours is ten times that.

227. In its 2010 Risk Evaluation and Mitigation Strategy ("REMS") for OxyContin, however, Purdue does not address the increased risk of respiratory depression and death from increasing dose, and instead advises prescribers that "dose adjustments may be made every 1-2 days"; "it is most appropriate to increase the q12h dose"; the "total daily dose can usually be increased by 25% to 50%"; and if "significant adverse reactions occur, treat them aggressively until they are under control, then resume upward titration."[69]

228. Endo sponsored a website, www.*Painknowledge.com*, which claimed that opioids may be increased until "you are on the right dose of medication for your pain," at which point further dose increases would not be required.

229. Endo also published on its website a patient education pamphlet entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*. In Q&A format, it asked, "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased ... You won't 'run out' of pain relief."

230. Marketing Defendants were aware of the greater dangers high dose opioids posed. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events" and that studies "appear to credibly

[69] Purdue Pharma, L.P., *OxyContin Risk Evaluation and Mitigation Strategy*, Purdue Pharma, https://web.archive.org/web/2/https://www.fda.gov/downloads/Drugs/DrugSafet%20y/PostmarketDrugSafetyInformationforPatientsandProviders/UCM220990.pdf, (last modified Nov. 2010).

suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality." A study of the Veterans Health Administration from 2004 to 2008 found the rate of overdose deaths is directly related to maximum daily dose.

f. Falsehood #6: Long-term Opioid Use Improves Functioning

231. Despite the lack of evidence of improved function and the existence of evidence to the contrary, the Marketing Defendants consistently promoted opioids for patients' function and quality of life because they viewed these claims as a critical part of their marketing strategies. In recalibrating the risk-benefit analysis for opioids, increasing the perceived benefits of treatment was necessary to overcome its risks.

232. Janssen, for example, promoted Duragesic as improving patients' functioning and work productivity through an ad campaign that included the following statements: "[w]ork, uninterrupted," "[l]ife, uninterrupted," "[g]ame, uninterrupted," "[c]hronic pain relief that supports functionality," and "[i]mprove[s] ... physical and social functioning."

233. Purdue noted the need to compete with this messaging, despite the lack of data supporting improvement in quality of life with OxyContin treatment:

> Janssen has been stressing decreased side effects, especially constipation, as well as patient quality of life, as supported by patient rating compared to sustained release morphine…We do not have such data to support OxyContin promotion. . . . In addition, Janssen has been using the "life uninterrupted" message in promotion of Duragesic for non-cancer pain, stressing that Duragesic "helps patients think less about their pain." This is a competitive advantage based on our inability to make any quality of life claims.[70]

234. Despite its acknowledgment that "[w]e do not have such data to support OxyContin promotion," Purdue ran a full-page ad for OxyContin in the Journal of the American Medical Association, proclaiming, "There Can Be Life With Relief," and showing a man happily fly-

[70] *Pain Killer*, *supra* n. 63, at 281.

fishing alongside his grandson, implying that OxyContin would help users' function. This ad earned a warning letter from the FDA, which admonished, "It is particularly disturbing that your November ad would tout 'Life With Relief' yet fail to warn that patients can die from taking OxyContin."[71]

235. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients. But the article cited as support for this in fact stated the contrary, noting the absence of long-term studies and concluding, "[f]or functional outcomes, the other analgesics were significantly more effective than were opioids."

236. A series of medical journal advertisements for OxyContin in 2012 presented "Pain Vignettes"—case studies featuring patients with pain conditions persisting over several months—that implied functional improvement. For example, one advertisement described a "writer with osteoarthritis of the hands" and implied that OxyContin would help him work more effectively.

237. Similarly, since at least May of 2011, Endo has distributed and made available on its website, www.*opana.com*, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like those of a construction worker or chef, misleadingly implying that the drug would provide long-term pain relief and functional improvement.

238. As noted above, Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which states as "a fact" that "opioids may make it easier for people to live normally." This guide features a man playing golf on the

[71] Chris Adams, *FDA Orders Purdue Pharma To Pull Its OxyContin Ads*, WALL STREET JOURNAL (Jan. 23, 2003, 12:01am), https://www.wsj.com/articles/SB1043259665976915824.

cover and lists examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. It assures patients that, "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'" Similarly, *Responsible Opioid Prescribing* (2007), sponsored and distributed by Teva, Endo, and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

239. In addition, Janssen's *Let's Talk Pain* website featured a video interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to "continue to function," falsely implying that her experience would be representative.

240. Endo's NIPC website, www.*Painknowledge.com*, claimed that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." In addition to "improved function," the website touted improved quality of life as a benefit of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make claims of functional improvement.

241. Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.

242. Mallinckrodt's website, in a section on responsible use of opioids, claims that "[t]he effective pain management offered by our medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."[72]

[72] Mallinckrodt Pharmaceuticals, Responsible Use,

243. The Marketing Defendants' claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. There are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients' pain and function long term. The FDA, for years, has made clear through warning letters to manufacturers the lack of evidence for claims that the use of opioids for chronic pain improves patients' function and quality of life.[73] Based upon a review of the existing scientific evidence, the CDC Guideline concluded that "there is no good evidence that opioids improve pain or function with long-term use."[74]

244. Consistent with the CDC's findings, substantial evidence exists demonstrating that opioid drugs are ineffective for the treatment of chronic pain and worsen patients' health. For example, a 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments. The few longer-term studies of opioid use had "consistently poor results," and "several studies have showed that Opioids for chronic pain may actually worsen pain and functioning…"[75] along with general health, mental health, and social

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http://www.mallinckrodt.com/corporate-responsibility/responsible-use, (last accessed July 16, 2018).

[73] The FDA has warned other drugmakers that claims of improved function and quality of life were misleading. *See* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (rejecting claims that Actavis' opioid, Kadian, had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that "patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."). The FDA's warning letters were available to Defendants on the FDA website.

[74] CDC Guideline at 20.

[75] Thomas Frieden and Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, at 1503, 374New Eng. J. Med., 4/21/16, at 1503. (April 21, 2016).

function. Over time, even high doses of potent opioids often fail to control pain, and patients exposed to such doses are unable to function normally.

245. On the contrary, the available evidence indicates opioids may worsen patients' health and pain. Increased duration of opioid use is strongly associated with increased prevalence of mental health disorders (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization. The CDC Guideline concluded that "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant."[76] According to the CDC, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[77]

246. As one pain specialist observed, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[78] In fact, research such as a 2008 study in the journal *Spine* has shown that pain sufferers prescribed opioids long-term suffered addiction that made them more likely to be disabled and unable to work.[79] Another study demonstrated that

[76] CDC Guideline at 2, 18.
[77] Thomas Frieden & Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, at 1503, 374 New Eng. J. Med. 1501-1504 (Apr. 21, 2016), doi: 10.1056/NEJMp1515917, http://www.nejm.org/doi/full/10.1056/NEJMp1515917.
[78] Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009), available at http://www.nbcms.org/en-us/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse.aspx?pageid=144&tabid=747.
[79] Jeffrey Dersh, et al., *Prescription opioid dependence is associated with poorer outcomes in disabling spinal disorders*, 33(20) Spine 2219-27 (Sept. 15, 2008).

injured workers who received a prescription opioid for more than seven days during the first six weeks after the injury were 2.2 times more likely to remain on work disability a year later than workers with similar injuries who received no opioids at all.[80] Yet, Marketing Defendants have not acknowledged, retracted, or corrected their false statements.

g. Falsehood #7: Alternative Forms of Pain Relief Pose Greater Risks Than Opioids

247. In materials they produced, sponsored, or controlled, the Marketing Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would favor opioids over other therapies such as over-the-counter acetaminophen or over-the-counter or prescription non-steroidal anti-inflammatory drugs ("NSAIDs").

248. For example, in addition to failing to disclose the risks of addiction, overdose, and death in promotional materials, the Marketing Defendants routinely ignored the risks of hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time,"[81] hormonal dysfunction,[82] decline in immune function; mental clouding, confusion, and dizziness,increased falls and fractures in the elderly,[83] neonatal abstinence syndrome (when an infant exposed to opioids

[80] Franklin, GM, et al., *Early opioid prescription and subsequent disability among workers with back injuries: the Disability Risk Identification Study Cohort*, 33 Spine 199, 201-202 (Jan. 15, 2008) doi: 10.1097/BRS.0b013e318160455c, https://www.ncbi.nlm.nih.gov/pubmed/18197107.
[81] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing,* Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).
[82] H.W. Daniell, Hypogonadism in men consuming sustained-action oral opioids, 3(5) J. Pain 377-84 (2001), https://www.ncbi.nlm.nih.gov/pubmed/14622741.
[83] *See* Bernhard M. Kuschel, et al., *The risk of fall injury in relation to commonly prescribed medications among older people – a Swedish case-control study*, 25 Eur. J. Pub. H. 527-32 (July 31, 2014), doi: 10.1093/eurpub/cku120, https://www.ncbi.nlm.nih.gov/pubmed/25085470

prenatally suffers withdrawal after birth), and potentially fatal interactions with alcohol or with benzodiazepines, which are used to treat anxiety and may be co-prescribed with opioids, particularly to veterans suffering from pain.[84]

249. The APF's *Treatment Options: A Guide for People Living with Pain*, sponsored by Purdue and Cephalon, warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. The publication falsely attributed 10,000 to 20,000 deaths annually to NSAID overdose, when the figure is actually closer to 3,200.[85]

250. Janssen sponsored *Finding Relief: Pain Management for Older Adults* (2009) that listed dose limitations as "disadvantages" of other pain medicines but omitted any discussion of risks from increased doses of opioids. *Finding Relief* described the advantages and disadvantages of NSAIDs on one page, and the "myths/facts" of opioids on the facing page. The disadvantages of NSAIDs are described as involving "stomach upset or bleeding," "kidney or liver damage if taken at high doses or for a long time," "adverse reactions in people with asthma," and "can increase the risk of heart attack and stroke." The only adverse effects of opioids listed are "upset stomach or sleepiness," which the brochure claims will go away, and constipation.

251. Endo's NIPC website, www.*Painknowledge.org*, contained a flyer called "Pain: Opioid Therapy." This publication listed opioids' adverse effects but with significant omissions, including hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance,

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[84] Karen H. Seal, et al., *Association of Mental Health Disorders With Prescription Opioids and High- Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) J. Am. Med. Ass'n 940-47, (March 7, 2012) doi:10.1001/jama.2012.234, https://jamanetwork.com/journals/jama/fullarticle/1105046.

[85] Robert E. Tarone, et al., *Nonselective Nonaspirin Nonsteroidal Anti-Inflammatory Drugs and Gastrointestinal Bleeding: Relative and Absolute Risk Estimates from Recent Epidemiologic Studies*, 11 Am. J. of Therapeutics 17-25 (2004), https://www.ncbi.nlm.nih.gov/pubmed/14704592.

dependence, addiction, and death.

252. In April 2007, Endo sponsored an article aimed at prescribers, published in *Pain Medicine News*, titled "Case Challenges in Pain Management: Opioid Therapy for Chronic Pain."[86] The article asserted:

253. Opioids represent a highly effective but controversial and often misunderstood class of analgesic medications for controlling both chronic and acute pain. The phenomenon of tolerance to opioids – the gradual waning of relief at a given dose – and fears of abuse, diversion, and misuse of these medications by patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief.[87]

254. To help allay these concerns, Endo emphasized the risks of NSAIDs as an alternative to opioids. The article included a case study that focused on the danger of extended use of NSAIDs, including that the subject was hospitalized with a massive upper gastrointestinal bleed believed to have resulted from his protracted NSAID use. In contrast, the article did not provide the same detail concerning the serious side effects associated with opioids.

255. Additionally, Purdue, acting with Endo, sponsored *Overview of Management Options*, a CME issued by the AMA in 2003, 2007, 2010, and 2013. The 2013 version remains available for CME credit. The CME taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

256. As a result of the Marketing Defendants' deceptive promotion of opioids over safer

[86] Charles E. Argoff, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*, Pain Med. News, http://www.painmedicinenews.com/download/ BtoB_Opana_WM.pdf, (link no longer available).
[87] *Id.*

and more effective drugs, opioid prescriptions increased even as the percentage of patients visiting a doctor for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits, as NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline in NSAID prescribing.[88]

h. Falsehood #8: OxyContin Provides Twelve Hours of Pain Relief

257. Purdue also dangerously misled doctors and patients about OxyContin's duration and onset of action, making the knowingly false claim that OxyContin would provide 12 hours of pain relief for most patients. As laid out below, Purdue made this claim for two reasons. First, it provided the basis for both Purdue's patent and its market niche, allowing it to both protect and differentiate itself from competitors. Second, it allowed Purdue to imply or state outright that OxyContin had a more even, stable release mechanism that avoided peaks and valleys and therefore the rush that fostered addiction and attracted abusers.

258. Purdue promotes OxyContin as an extended-release opioid, but the oxycodone does not enter the body on a linear rate. OxyContin works by releasing a greater proportion of oxycodone into the body upon administration, and the release gradually tapers, as illustrated in the following chart, which was apparently adapted from Purdue's own sales materials.

[88] M. Daubresse, et al., *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010*, 51(10) Med. Care, 870-878 (2013). "For back pain alone, the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined from 39.9% to 24.5% of these visits; and referrals to physical therapy remained steady." *See also*, J. Mafi, et al., *Worsening Trends in the Management and Treatment of Back Pain*, 173(17) J. of the Am Med. Ass'n Internal Med. 1573, 1573 (2013).

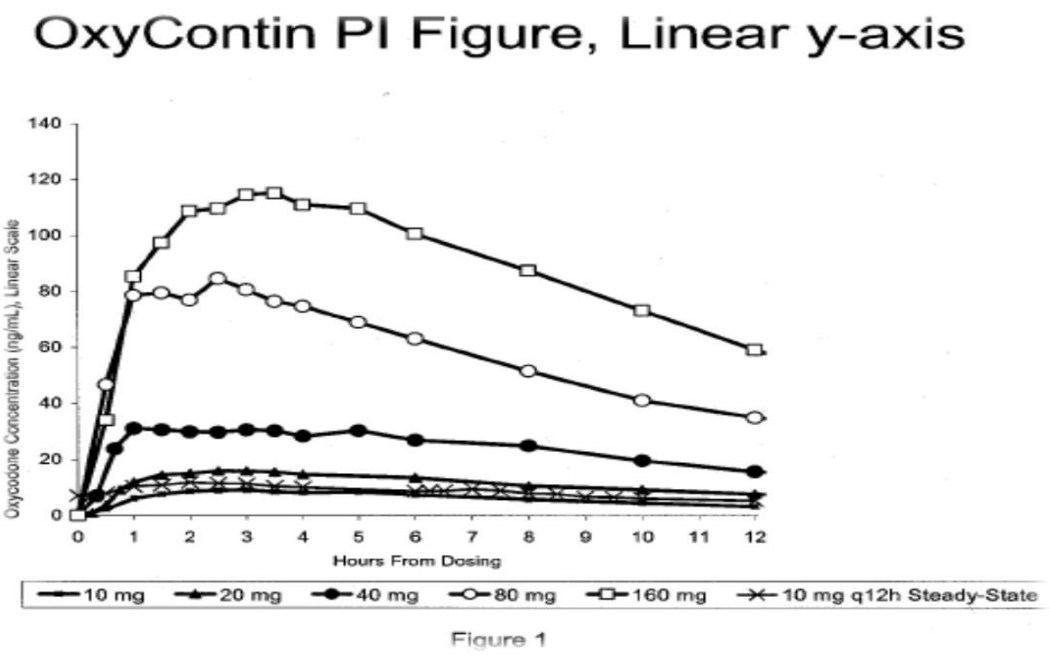


Figure 1

259. The reduced release of the drug over time means that the OxyContin no longer provides the same level of pain relief; as a result, in many patients, OxyContin does not last for the twelve hours for which Purdue promotes it—a fact that Purdue has known at all times relevant to this action.

260. OxyContin tablets provide an initial absorption of approximately 40% of the active medicine. This has a two-fold effect. First, the initial rush of nearly half of the powerful opioid triggers a powerful psychological response. OxyContin thus behaves more like an immediate release opioid, which Purdue itself once claimed was more addicting in its original 1995 FDA-approved drug label. Second, the initial burst of oxycodone means that there is less of the drug at the end of the dosing period, which results in the drug not lasting for a full twelve hours and precipitates withdrawal symptoms in patients, a phenomenon known as "end of dose" failure. (The FDA found in 2008 that a "substantial number" of chronic pain patients will experience end-of-dose failure with OxyContin.)

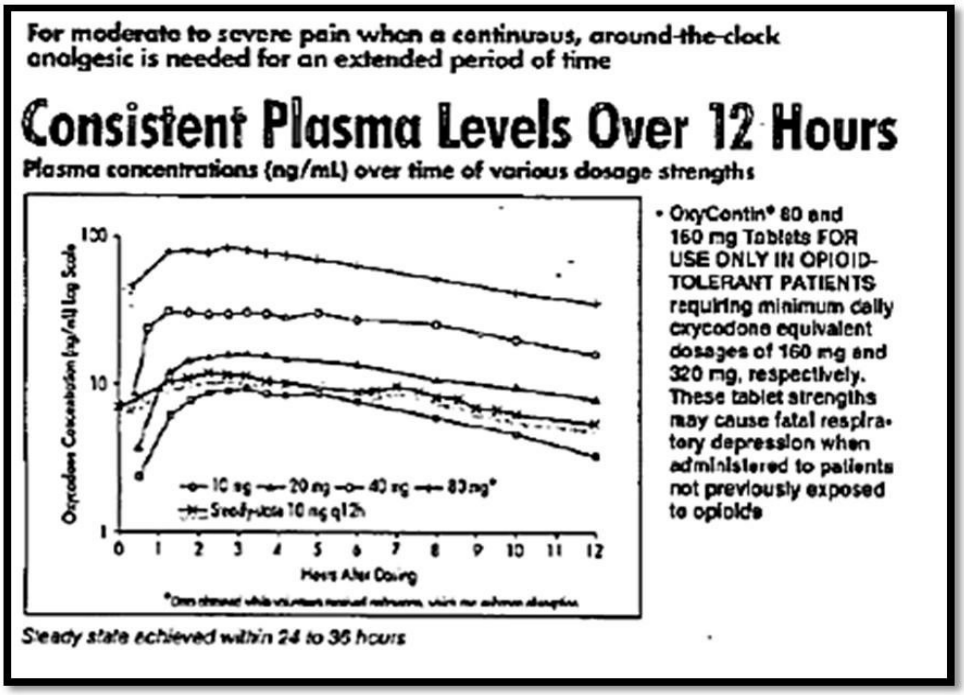
261. End-of-dose failure renders OxyContin even more dangerous because patients

begin to experience withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin's 12-hour dosing "the perfect recipe for addiction."[89] Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

262. It was Purdue's decision to submit OxyContin for approval with 12-hour dosing. While the OxyContin label indicates that "[t]here are no well-controlled clinical studies evaluating the safety and efficacy with dosing more frequently than every 12 hours," that is because Purdue has conducted no such studies.

263. Purdue nevertheless has falsely promoted OxyContin as if it were effective for a full twelve hours. Its advertising in 2000 included claims that OxyContin provides "Consistent Plasma Levels Over 12 Hours." That claim was accompanied by a chart, mirroring the chart on the previous page. However, this version of the chart deceptively minimized the rate of end-of-dose failure by depicting 10 mg in a way that it appeared to be half of 100 mg in the table's y-axis. That chart, shown below, depicts the same information as the chart above, but does so in a way that makes the absorption rate appear more consistent:

[89] Harriet Ryan, et al., *'You Want a Description of Hell?' OxyContin's 12-Hour Problem*, LOS ANGELES TIMES (May 5, 2016), http://www.latimes.com/projects/oxycontin-part1/.



264. Purdue's 12-hour messaging was key to its competitive advantage over short-acting opioids that required patients to wake in the middle of the night to take their pills. Purdue advertisements also emphasized "Q12h" dosing. These include an advertisement in the February 2005 *Journal of Pain* and 2006 *Clinical Journal of Pain* featuring an OxyContin logo with two pill cups, reinforcing the twice-a-day message. A Purdue memo to the OxyContin launch team stated that "OxyContin's positioning statement is 'all of the analgesic efficacy of immediate-release oxycodone, with convenient q12h dosing,'" and further that "[t]he convenience of q12h dosing was emphasized as the most important benefit."[90]

265. Purdue executives therefore maintained the messaging of twelve-hour dosing even when many reports surfaced that OxyContin did not last twelve hours. Instead of acknowledging a need for more frequent dosing, Purdue instructed its representatives to push higher-strength pills,

[90] Purdue Meeting Memo, *OxyContin launch*, LOS ANGELES TIMES (May 5, 2016), http://documents.latimes.com/oxycontin-launch-1995/.

even though higher dosing carries its own risks, as noted above. Higher dosing also means that patients will experience higher highs and lower lows, increasing their craving for their next pill. Nationwide, based on an analysis by the Los Angeles Times, more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day—which converts to the 90 MED (morphine equivalent dose) that the CDC Guideline urges prescribers to "avoid" or "carefully justify."[91]

266. The information that OxyContin did not provide pain relief for a full twelve hours was known to Purdue, and Purdue's competitors, but was not disclosed to prescribers. Purdue's knowledge of some pain specialists' tendency to prescribe OxyContin three times per day instead of two is apparent from MEDWATCH Adverse Event reports for OxyContin.

267. Even Purdue's competitor, Endo, was aware of the problem; Endo attempted to position its Opana ER drug as offering "durable" pain relief, which Endo understood to suggest a contrast to OxyContin. Opana ER advisory board meetings featured pain specialists citing lack of 12-hour dosing as a disadvantage of OxyContin. Endo even ran advertisements for Opana ER referring to "real" 12-hour dosing.

268. For example, in a 1996 sales strategy memo from a Purdue regional manager, the manager emphasized that representatives should "convinc[e] the physician that there is no need" for prescribing OxyContin in shorter intervals than the recommended 12-hour interval, and instead the solution is prescribing higher doses."[92] One sales manager instructed her team that anything shorter than 12-hour dosing "needs to be nipped in the bud. NOW!!"[93]

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[91] CDC Guideline at 16.

[92] Southern Region Memo to Mr. B. Gergely, *Sales manager on 12-hour dosing*, LOS ANGELES TIMES (May 5, 2016), http://documents.latimes.com/sales-manager-on12-hour-dosing-1996/.

[93] Harriet Ryan, et al., *'You Want a Description of Hell?' OxyContin's 12-Hour Problem*, LOS ANGELES TIMES (May 5, 2016), http://www.latimes.com/projects/oxycontin-part1/.

269. Purdue's failure to disclose the prevalence of end-of-dose failure meant that prescribers were misinformed about the advantages of OxyContin in a manner that preserved Purdue's competitive advantage and profits, at the expense of patients, who were placed at greater risk of overdose, addiction, and other adverse effects.

i. Falsehood #9: New Formulations of Certain Opioids Successfully Deter Abuse

270. Rather than take the widespread abuse of and addiction to opioids as reason to cease their untruthful marketing efforts, Marketing Defendants Purdue and Endo seized them as a opportunity to ccompete. These companies developed and oversold "abuse-deterrent formulations" ("ADF") opioids as a solution to opioid abuse and as a reason that doctors could continue to safely prescribe their opioids, as well as an advantage of these expensive branded drugs over other opioids. These Defendants' false and misleading marketing of the benefits of their ADF opioids preserved and expanded their sales and falsely reassured prescribers thereby prolonging the opioid epidemic. Other Marketing Defendants, including Actavis and Mallinckrodt, also promoted their branded opioids as formulated to be less addictive or less subject to abuse than other opioids.

271. The CDC Guideline confirms that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes." Tom Frieden, the former Director of the CDC, reported that his staff could not find "any evidence showing the updated opioids [ADF opioids] actually reduce rates of addiction, overdoses, or death."

i. Purdue's Deceptive Marketing of Reformulated OxyContin and Hysingla ER

272. Reformulated ADF OxyContin was approved by the FDA in April 2010. It was not

until 2013 that the FDA, in response to a citizen petition filed by Purdue, permitted reference to the abuse-deterrent properties in its label. When Hysingla ER (extended-release hydrocodone) launched in 2014, the product included similar abuse-deterrent properties and limitations. But in the beginning, the FDA made clear the limited claims that could be made about ADF, noting that no evidence supported claims that ADF prevented tampering, oral abuse, or overall rates of abuse.

273. Purdue introduced reformulated ADF OxyContin shortly before generic versions of OxyContin were to become available. By so doing, Purdue anticipated and countered a threat to its market share and the price it could charge for OxyContin. Purdue nonetheless touted its introduction of ADF opioids as evidence of its good corporate citizenship and commitment to address the opioid crisis.

274. Despite its self-proclaimed good intention, Purdue merely continued its generally deceptive tactics with respect to ADF. Purdue sales representatives regularly overstated and misstated the evidence for and impact of the abuse-deterrent features of these opioids. Specifically, Purdue sales representatives: claimed that Purdue's ADF opioids prevent tampering and that its ADFs could not be crushed or snorted; claimed that Purdue's ADF opioids reduce opioid abuse and diversion; asserted or suggested that its ADF opioids are non-addictive or less addictive; asserted or suggested that Purdue's ADF opioids are safer than other opioids, could not be abused or tampered with, and were not sought out for diversion; and failed to disclose that Purdue's ADF opioids do not impact oral abuse or misuse.

275. If pressed, Purdue acknowledged that perhaps some "extreme" patients might still abuse the drug but claimed the ADF features protect the majority of patients. These misrepresentations and omissions are misleading and contrary to Purdue's ADF labels, Purdue's own information, and publicly available data.

276. Purdue knew or should have known that reformulated OxyContin is not more tamper-resistant than the original OxyContin and is still regularly tampered with.

277. In 2009, the FDA noted in permitting ADF labeling that "the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)." In the 2012 medical office review of Purdue's application to include an abuse-deterrence claim in its label for OxyContin, the FDA noted that the overwhelming majority of deaths linked to OxyContin were associated with oral consumption, and that only 2% of deaths were associated with recent injection and only 0.2% with snorting the drug.

278. The FDA's Director of the Division of Epidemiology stated in September 2015 that no data that she had seen suggested the reformulation of OxyContin "actually made a reduction in abuse," between continued oral abuse, shifts to injection of other drugs (including heroin), and defeat of the ADF mechanism. Even Purdue's own funded research shows that half of OxyContin abusers continued to abuse the drug orally after the reformulation rather than shift to other drugs.

279. A 2013 article presented by Purdue employees, based on review of data from poison control centers, concluded that ADF OxyContin can reduce abuse, but ignored important negative findings. The article revealed that abuse merely shifted to other drugs and that, when the actual incidence of harmful exposures was calculated, there were more harmful exposures to opioids after the reformulation of OxyContin. In short, the article deceptively emphasized the advantages and ignored the disadvantages of ADF OxyContin.

280. Websites and message boards used by drug abusers, such as www.*bluelight.org* and www.*reddit.com*, report a variety of ways to tamper with OxyContin and Hysingla ER, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which a tablet is dissolved. Purdue has been aware of these methods of abuse for more than a decade.

281. One-third of the patients in a 2015 study defeated the ADF mechanism and were able to continue inhaling or injecting the drug. To the extent that the abuse of Purdue's ADF opioids was reduced, there was no meaningful reduction in opioid abuse overall, as many users simply shifted to other opioids such as heroin.

282. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew a supplemental new drug application related to reformulated OxyContin one day before FDA staff was to release its assessment of the application. The staff review preceded an FDA advisory committee meeting related to new studies by Purdue "evaluating the misuse and/or abuse of reformulated OxyContin" and whether those studies "have demonstrated that the reformulated product has a meaningful impact on abuse."[94] In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that Purdue never presented the data to the FDA because the data would not have supported claims that OxyContin's ADF properties reduced abuse or misuse.

283. Despite its own evidence of abuse, and the lack of evidence regarding the benefit of Purdue's ADF opioids in reducing abuse, Dr. J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's ADF opioids are being abused in large numbers. Purdue's recent advertisements in national newspapers also continues to claim its ADF opioids as evidence of its efforts to reduce opioid abuse, continuing to mislead prescribers, patients, payors, and the public about the efficacy of its actions.

ii. Endo's Deceptive Marketing of Reformulated Opana ER

284. Opana ER was particularly likely to be tampered with and abused. That is because

[94] Meeting Notice, Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting, May 25, 2015, 80 FR 30686.

Opana ER has lower "bioavailability" than other opioids, meaning that the active pharmaceutical ingredient (the "API" or opioid) does not absorb into the bloodstream as rapidly as other opioids when taken orally. Additionally, when swallowed whole, the extended-release mechanism remains intact, so that only 10% of Opana ER's API is released into the patient's bloodstream relative to injection; when it is taken intranasally, that rate increases to 43%. The larger gap between bioavailability when consumed orally versus snorting or injection, the greater the incentive for users to manipulate the drug's means of administration.

285. In December 2011, Endo obtained approval for a new formulation of Opana ER that added a hard coating that the company claimed made it crush-resistant.

286. Even prior to its approval, the FDA advised Endo that it could not market the new Opana ER as abuse-deterrent.

287. Nonetheless, in August of 2012, Endo submitted a citizen petition asking the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, both in that it was less able to be crushed and snorted and that it was resistant to injection by syringe. Borrowing a page from Purdue's playbook, Endo announced it would withdraw original Opana ER from the market and sought a determination that its decision was made for safety reasons (its lack of abuse-deterrence), which would prevent generic copies of original Opana ER.

288. Endo then sued the FDA, seeking to force expedited consideration of its citizen petition. The court filings confirmed Endo's true motives: in a declaration submitted with its lawsuit, Endo's chief operating officer indicated that a generic version of Opana ER would decrease the company's revenue by up to $135 million per year. Endo also claimed that if the FDA did not block generic competition, $125 million, the amount Endo spent on developing the

reformulated drug to "promote the public welfare", would be lost.[95] The FDA responded that: "Endo's true interest in expedited FDA consideration stems from business concerns rather than protection of the public health."[96]

289. Despite Endo's purported concern with public safety, not only did Endo continue to distribute original, admittedly unsafe Opana ER for nine months after the reformulated version became available, it declined to recall original Opana ER despite its dangers. In fact, Endo claimed in September 2012 to be "proud" that "almost all remaining inventory" of the original Opana ER had "been utilized."[97]

290. In its citizen petition, Endo asserted that redesigned Opana ER had "safety advantages." Endo even relied on its rejected assertion that Opana was less crushable to argue that it developed Opana ER for patient safety reasons and that the new formulation would help, for example, "where children unintentionally chew the tablets prior to an accidental ingestion."[98]

291. However, in a 2013 decision rejecting the petition, the FDA found that "study data show that the reformulated version's extended-release features can be compromised when subjected to ... cutting, grinding, or chewing." The FDA also determined that "reformulated Opana ER" could also be "readily prepared for injections and more easily injected[.]" In fact, the FDA warned that preliminary data—including in Endo's own studies—suggested that a higher

[95] Plaintiff's Opposition to Defendants' and Intervenor's Motions to Dismiss and Plaintiff's Reply in Support of Motion for Preliminary Injunction ("Endo Br."), *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al*., No. 1:12-cv-01936, Doc. 23 at 20 (D.D.C. Dec.14, 2012).
[96] Defendants' Response to the Court's November 30, 2012 Order, *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936, Doc. 9 at 6 (D.D.C. Dec. 3, 2012).
[97] *Id.*; Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl.) *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936, Doc. 18-4 (D.D.C. Dec. 9, 2012).
[98] CP, FDA Docket 2012-8-0895, at 2.

percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation.

292. In 2009, only 3% of Opana ER abuse was by intravenous means. Since the reformulation, injection of Opana ER has increased by more than 500%. Endo's own data, presented in 2014, found that between October 2012 and March 2014, 64% of abusers of Opana ER did so by injection, compared with 36% for the old formulation.[99] The transition into injection of Opana ER made the drug even less safe than the original formulation. Injection carries risks of HIV, hepatitis C, and, in reformulated Opana ER's specific case, the blood-clotting disorder thrombotic thrombocytopenic purpura (TTP), which can cause kidney failure.

293. Publicly, Endo sought to minimize the problem. On a 2013 call with investors, when asked about an outbreak of TTP in Tennessee from injecting Opana ER, Endo sought to limit its import by assigning it to "a very, very distinct area of the country."

294. Despite its knowledge that Opana ER was widely abused and injected, Endo marketed the drug as tamper-resistant and abuse-deterrent. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that based on the company's detailing elsewhere, Endo sales representatives informed doctors that Opana ER was abuse-deterrent, could not be tampered with, and was safe. In addition, sales representatives did not disclose evidence that Opana was easier to abuse intravenously and, if pressed by prescribers, claimed that while outlier patients might find a way to abuse the drug, most would be protected.

295. A review of national surveys of prescribers regarding their "take-aways" from

[99] Theresa Cassidy, et al., *The Changing Abuse Ecology: Implications for Evaluating the Abuse Pattern of Extended-Release Oxymorphone and Abuse-Deterrent Opioid Formulations*, Inflexxion (Sept. 7, 2014)), https://www.inflexxion.com/changing-abuse-ecology-extended-release-oxymorphone/.

pharmaceutical detailing confirms that prescribers remember being told Opana ER was tamper-resistant. Endo also tracked messages that doctors took from its in-person marketing. Among the advantages of Opana ER, according to participating doctors, was its "low abuse potential." For example, a June 14, 2012 Endo press release announced, "the completion of the company's transition of its Opana ER franchise to the new formulation designed to be crush resistant."

296. The press release further stated that: "We firmly believe that the new formulation of Opana ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers." The press release described the old formulation of Opana as subject to abuse and misuse, but failed to disclose the absence of evidence that reformulated Opana was any better. In September 2012, another Endo press release stressed that reformulated Opana ER employed "INTAC Technology" and continued to describe the drug as "designed to be crush-resistant."

297. Similarly, journal advertisements that appeared in April 2013 stated Opana ER was "designed to be crush resistant." A January 2013 article in Pain Medicine News, based in part on an Endo press release, described Opana ER as "crush-resistant." This article was posted on the *Pain Medicine News* website, which was accessible to patients and prescribers.

298. In March 2017, because Opana ER could be "readily prepared for injection" and was linked to outbreaks of HIV and TTP, an FDA advisory committee recommended that Opana be withdrawn from the market. The FDA adopted this recommendation on June 8, 2017.[100] Endo

[100] Press Release, FDA, FDA requests removal of Opana ER for risks related to abuse, (June 8, 2017), *available at* https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm

announced on July 6, 2017 that it would agree to stop marketing and selling Opana ER.[101] However, by this point, the damage had been done. Even then, Endo continued to insist, falsely, that it "has taken significant steps over the years to combat misuse and abuse."

iii. Other Marketing Defendants' Misrepresentations Regarding Abuse Deterrence

299. Mallinckrodt promoted both Exalgo (extended-release hydromorphone) and Xartemis XR (oxycodone and acetaminophen) as specifically formulated to reduce abuse. For example, Mallinckrodt's promotional materials stated that "the physical properties of EXALGO may make it difficult to extract the active ingredient using common forms of physical and chemical tampering, including chewing, crushing and dissolving."[102] One member of the FDA's Controlled Substance Staff, however, noted in 2010 that hydromorphone has "a high abuse potential comparable to oxycodone" and further stated that "we predict that Exalgo will have high levels of abuse and diversion."

300. With respect to Xartemis XR, Mallinckrodt's promotional materials stated that "XARTEMIS XR has technology that requires abusers to exert additional effort to extract the active ingredient from the large quantity of inactive and deterrent ingredients."[103] In anticipation of Xartemis XR's approval, Mallinckrodt added 150-200 sales representatives to promote it, and CEO Mark Trudeau said the drug could generate "hundreds of millions in revenue."[104]

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[101] Press Release, Endo International plc, Endo Provides Update on Opana ER, (July 6, 2017), *available at* https://www.prnewswire.com/news-releases/endo-provides-update-on-opana-er-300484191.html.

[102] Mallinckrodt Press Release, Medtronic, *FDA Approves Mallinckrodt's EXALGO® (hydromorphone HCl) Extended-Release Tablets 32 mg (CII) for Opioid-Tolerant Patients with Moderate-to-Severe Chronic Pain* (Aug. 27, 2012), *available at* http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=2004159.

[103] Mallinckrodt, *Responsible Use of Opioid Pain Medications* (Mar. 7, 2014).

[104] Samantha Liss, *Mallinckrodt banks on new painkillers for sales*, ST. LOUIS BUSINESS JOURNAL (Dec. 30, 2013), http://argentcapital.com/mallinckrodt-banks-on-new-painkillers-for-sales/.

301. While Marketing Defendants promote patented technology as the solution to opioid abuse and addiction, none of their "technology" addresses the most common form of abuse—oral ingestion—and their statements regarding abuse-deterrent formulations give the misleading impression that these reformulated opioids can be prescribed safely.

302. In sum, each of the nine categories of misrepresentations discussed above regarding the use of opioids to treat chronic pain was either not supported by or was contrary to the scientific evidence. In addition, the Defendants' misrepresentations and omissions as set in this Complaint are misleading and contrary to the Marketing Defendants' products' labels.

2. The Marketing Defendants Disseminated Their Misleading Messages About Opioids Through Multiple Channels

303. The Marketing Defendants' false marketing campaign not only targeted the medical community who had to treat chronic pain, but also patients who experience chronic pain.

304. The Marketing Defendants utilized various channels to carry out their marketing scheme of targeting the medical community and patients with deceptive information about opioids: (1) "Front Groups" with the appearance of independence from the Marketing Defendants; (2) so-called "key opinion leaders" ("KOLs"), that is, doctors who were paid by the Marketing Defendants to promote their pro-opioid message; (3) CME programs controlled and/or funded by the Marketing Defendants; (4) branded advertising; (5) unbranded advertising; (6) publications; (7) direct, targeted communications with prescribers by sales representatives or "detailers;" and (8) speakers bureaus and programs.

3. The Marketing Defendants Deceptively Directed Front Groups to Promote Opioid Use

305. Patient advocacy groups and professional associations also became vehicles to reach prescribers, patients, and policymakers. Marketing Defendants exerted influence and effective control over the messaging by these groups by providing major funding directly to them,

as well as through KOLs who served on their boards. These "Front Groups" put out patient education materials, treatment guidelines and CMEs that supported the use of opioids for chronic pain, overstated the benefits of opioids, and understated their risks.[105] Defendants funded these Front Groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages—often at the expense of the Front Groups own constituencies.

306. "Patient advocacy organizations and professional societies like the Front Groups 'play a significant role in shaping health policy debates, setting national guidelines for patient treatment, raising disease awareness, and educating the public.'"[106] "Even small organizations—with 'their large numbers and credibility with policymakers and the public'—have 'extensive influence in specific disease areas.' Larger organizations with extensive funding and outreach capabilities 'likely have a substantial effect on policies relevant to their industry sponsors.'"[107] Indeed, the U.S. Senate's report, *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*,[108] which arose out of a 2017 Senate investigation and, drawing on disclosures from Purdue, Janssen, Insys, and other opioid manufacturers, "provides the first comprehensive snapshot of the financial connections between opioid manufacturers and advocacy groups and professional societies operating in the area of Office opioids policy,"[109] found that the Marketing Defendants made millions of dollars' worth of

[105] U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Members' Office, *Fueling an Epidemic, Report Two: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups* (Feb. 12, 2018), https://www.hsdl.org/?abstract&did=808171 ("*Fueling an Epidemic*"), at p. 3.
[106] *Id.* at p. 2.
[107] *Id.*
[108] *Id.* at p. 1.
[109] *Id.*

contributions to various Front Groups.[110]

307. The Marketing Defendants also "made substantial payments to individual group executives, staff members, board members, and advisory board members" affiliated with the Front Groups subject to the Senate Committee's study.[111]

308. As the Senate *Fueling an Epidemic* Report found, the Front Groups "amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain."[112] They also "lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for over prescription and misbranding."[113]

309. The Marketing Defendants took an active role in guiding, reviewing, and approving many of the false and misleading statements issued by the Front Groups, ensuring that Defendants were consistently in control of their content. By funding, directing, editing, approving, and distributing these materials, Defendants exercised control over and adopted their false and deceptive messages and acted in concert with the Front Groups and through the Front groups, with each working with the other to deceptively promote the use of opioids for the treatment of chronic pain.

a. <u>American Pain Foundation</u>

310. The most prominent of the Front Groups was the American Pain Foundation ("APF"). While APF held itself out as an independent patient advocacy organization, in reality it

[110] *Id.* at p. 3.
[111] *Id.* at p. 10.
[112] *Id.* at 12-15.
[113] *Id.* at 12.

received 90% of its funding in 2010 from the drug and medical-device industry, including from Defendants Purdue, Endo, Janssen and Cephalon. APF received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. By 2011, APF was entirely dependent on incoming grants from Defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. Endo was APF's largest donor and provided more than half of its $10 million in funding from 2007 to 2012.

311. For example, APF published a guide sponsored by Cephalon and Purdue titled *Treatment Options: A Guide for People Living with Pain* and distributed 17,200 copies of this guide in one year alone, according to its 2007 annual report. This guide contains multiple misrepresentations regarding opioid use which are discussed *supra*.

312. APF also developed the National Initiative on Pain Control ("NIPC"), which ran a facially unaffiliated website, *www.painknowledge.org*. NIPC promoted itself as an education initiative led by its expert leadership team, including purported experts in the pain management field. NIPC published unaccredited prescriber education programs (accredited programs are reviewed by a third party and must meet certain requirements of independence from pharmaceutical companies), including a series of "dinner dialogues." But it was Endo that substantially controlled NIPC, by funding NIPC projects, developing, specifying, and reviewing its content, and distributing NIPC materials. Endo's control of NIPC was such that Endo listed it as one of its "professional education initiative[s]" in a plan Endo submitted to the FDA. Yet, Endo's involvement in NIPC was nowhere disclosed on the website pages describing NIPC or on *www.painknowledge.org*. Endo estimated it would reach 60,000 prescribers through NIPC.

313. APF was often called upon to provide "patient representatives" for the Marketing Defendants' promotional activities, including for Purdue's "*Partners Against Pain*" and Janssen's

"*Let's Talk Pain*." Although APF presented itself as a patient advocacy organization, it functioned largely as an advocate for the interests of the Marketing Defendants, not patients. As Purdue told APF in 2001, the basis of a grant to the organization was Purdue's desire to strategically align its investments in nonprofit organizations that shared its business interests.

314. In practice, APF operated in close collaboration with Defendants, submitting grant proposals seeking to fund activities and publications suggested by Defendants and assisting in marketing projects for Defendants.

315. This alignment of interests was expressed most forcefully in the fact that Purdue hired APF to provide consulting services on its marketing initiatives. Purdue and APF entered into a "Master Consulting Services" Agreement on September 14, 2011. That agreement gave Purdue substantial rights to control APF's work related to a specific promotional project. Moreover, based on the assignment of particular Purdue "contacts" for each project and APF's periodic reporting on their progress, the agreement enabled Purdue to be regularly aware of the misrepresentations APF was disseminating regarding the use of opioids to treat chronic pain in connection with that project. The agreement gave Purdue—but not APF—the right to end the project (and, thus, APF's funding) for any reason.

316. APF's Board of Directors was largely comprised of doctors who were on the Marketing Defendants' payrolls, either as consultants or as speakers for medical events. The close relationship between APF and the Marketing Defendants demonstrates APF's lack of independence in its finances, management, and mission, and APF's willingness to allow Marketing Defendants to control its activities and messages supports an inference that each Defendant that worked with it was able to exercise editorial control over its publications—even when Defendants' messages contradicted APF's internal conclusions.

317. In May 2012, the U.S. Senate Finance Committee began looking into APF to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF then "cease[d] to exist, effective immediately." Without support from Marketing Defendants, to whom APF could no longer be helpful, APF was no longer financially viable.

b. American Academy of Pain Medicine and the American Pain Society

318. The American Academy of Pain Medicine ("AAPM") and the American Pain Society ("APS") are professional medical societies, each of which received substantial funding from Defendants from 2009 to 2013. In 1997, AAPM issued a "consensus" statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.[114] The Chair of the committee that issued the statement, Dr. J. David Haddox, was at the time a paid speaker for Purdue. The sole consultant to the committee was Dr. Russell Portenoy, who was also a spokesperson for Purdue. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM's website.

319. AAPM's corporate council includes Purdue, Depomed, Teva and other pharmaceutical companies. AAPM's past presidents include Haddox (1998), Dr. Scott Fishman ("Fishman") (2005), Dr. Perry G. Fine ("Fine") (2011) and Dr. Lynn R. Webster ("Webster") (2013), all of whose connections to the opioid manufacturers are well-documented as set forth below.

320. Fishman, who also served as a KOL for Marketing Defendants, stated that he would

[114] *The Use of Opioids for the Treatment of Chronic Pain*, APS & AAPM (1997), a*vailable at* http://www.stgeorgeutah.com/wp-content/uploads/2016/05/OPIOIDES.DOLORCRONICO.pdf (last accessed August 1, 2018).

place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."[115]

321. AAPM has received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations.

322. More specifically, Purdue paid $725,584.95 from 2012-2017 to AAPM.[116] Janssen paid $83,975 from 2012-2017 to AAPM.[117] Insys paid $57,750 from 2012-2017 to AAPM.[118] Endo funded AAPM CMEs. Teva is on AAPM's corporate relations council.

323. As to APS, Purdue paid $542,259.52 from 2012-2017.[119] Janssen paid $88,500 from 2012-2017.[120] Insys paid $22,965 from 2012-2017.[121]

324. AAPM describes its annual meeting as an "exclusive venue" for offering Continuing Medical Education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of

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[115] Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), *available at* http://www.medscape.org/viewarticle/500829.
[116] *Id.*
[117] *Fueling an Epidemic Part Two.*
[118] *Id.*
[119] *Fueling an Epidemic Report Two*, *Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocary Groups*, U.S. Senate Homeland Security & Governmental Affairs Committee, https://www.hsdl.org/?abstract&did=808171 (last accessed August 1, 2018) (hereinafter referred to as "*Fueling an Epidemic Part Two*")
[120] *Id.*
[121] *Id.*

the council and presented deceptive programs to doctors who attended this annual event. The conferences sponsored by AAPM heavily emphasized CME sessions on opioids – 37 out of roughly 40 at one conference alone.

325. AAPM's staff understood that they and their industry funders were engaged in a common task. Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

326. In 1996, AAPM and APS jointly issued a consensus statement, "The Use of Opioids for the Treatment of Chronic Pain," which endorsed opioids to treat chronic pain and claimed that the risk of a patients' addiction to opioids was low. Dr. David Haddox, who co-authored the AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011.

327. AAPM and APS issued their own guidelines in 2009 ("2009 Guidelines"). AAPM, with the assistance, prompting, involvement, and funding of Defendants, issued the treatment guidelines discussed herein, and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines, including KOL Dr. Fine, received support from Defendants Janssen, Cephalon, Endo, and Purdue. Of these individuals, six received support from Purdue, eight from Teva, nine from Janssen, and nine from Endo.

328. Dr. Gilbert Fanciullo, now retired as a professor at Dartmouth College's Geisel School of Medicine, who served on the AAPM/APS Guidelines panel, has since described them as "skewed" by drug companies and "biased in many important respects," including the high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

329. The 2009 Guidelines have been a particularly effective channel of deception. They

have influenced not only treating physicians, but also the scientific literature on opioids; they were reprinted in the Journal of Pain, have been cited hundreds of times in academic literature, were disseminated during the relevant time period, and were and are available online. Treatment guidelines are especially influential with primary care physicians and family doctors to whom Marketing Defendants promoted opioids and whose lack of specialized training in pain management and opioids makes them more reliant on, and less able to evaluate, these guidelines.

330. For that reason, the CDC has recognized that treatment guidelines can "change prescribing practices."[122]

331. The 2009 Guidelines are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain.

332. The Marketing Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions, their involvement in the development of the Guidelines, or their financial backing of the authors of these Guidelines. For example, a speaker presentation prepared by Endo in 2009 titled *The Role of Opana ER in the Management of Moderate to Severe Chronic Pain* relies on the AAPM/APS 2009 Guidelines while omitting their disclaimer regarding the lack of evidence for recommending the use of opioids for chronic pain.

c. FSMB

333. The Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline

[122] Centers for Disease Control and Prevention, *CDC Guideline for Prescribing Opioids for Chronic Pain*, (March 15, 2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm, (hereinafter "2016 CDC Guideline").

physicians.

334. The FSMB finances opioid- and pain-specific programs through grants from Defendants.

335. Since 1998, the FSMB has been developing treatment guidelines for the use of opioids for the treatment of pain. The 1998 version, Model Guidelines for the Use of Controlled Substances for the Treatment of Pain ("1998 Guidelines") was produced "in collaboration with pharmaceutical companies." The 1998 Guidelines—that the pharmaceutical companies helped author—taught not that opioids could be appropriate in only limited cases after other treatments had failed, but that opioids were "essential" for treatment of chronic pain, including as a first prescription option.

336. A 2004 iteration of the 1998 Guidelines and the 2007 book, *Responsible Opioid Prescribing*, also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians nationwide, including in Perry County.

337. FSMB's 2007 publication *Responsible Opioid Prescribing* was backed largely by drug manufacturers, including Purdue, Endo and Cephalon. Purdue paid $100,000 for the printing and distribution of FSMB's Guidelines.[123]

338. The publication also received support from the American Pain Foundation (APF) and the American Academy of Pain Medicine (AAPM). The publication was written by Dr. Fishman, and Dr. Fine served on the Board of Advisors. In all, 163,131 copies of *Responsible*

[123] John Fauber, *Follow the Money: Pain, Policy, and Profit*, MILWAUKEE JOURNAL SENTINEL/MEDPAGE TODAY (Feb. 19, 2012), https://www.medpagetoday.com/neurology/painmanagement/31256.

Opioid Prescribing were distributed by state medical boards.[124] The FSMB website describes the book as "the leading continuing medical education (CME) activity for prescribers of opioid medications." This publication asserted that opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins; that pain is under-treated, and that patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient.[125]

339. The Marketing Defendants relied on the 1998 Guidelines to convey the alarming message that "under-treatment of pain" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors' fear of discipline on its head: doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be punished if they failed to prescribe opioids to their patients with chronic pain.

340. Dr. Fishman said that he did not receive any payments from FSMB or any royalties from the publisher because he wanted to avoid the perception of a potential conflict of interest in his authorship of the book or for the ongoing efforts of FSMB. This is because prior to 2011, he had been scrutinized for his involvement with the front groups/manufacturers and accepting payments.[126]

341. The Manufacturing Defendants made additional contributions to the FSMB to

[124] Email from Dr. Scott Fishman to Charles Ornstein, ProPublica (Dec. 15, 2011), https://assets.documentcloud.org/documents/279033/fishman-responses-to-propublica.pdf.
[125] Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide* 8-9 (Waterford Life Sciences 2007).
[126] Email from Dr. Scott Fishman to Charles Ornstein, ProPublica (Dec. 15, 2011), https://assets.documentcloud.org/documents/279033/fishman-responses-to-propublica.pdf.

further their misleading advertising. For example, Purdue paid FSMB $822,400.06 over 8 years.[127] Cephalon paid FSMB $180,000 over a 3-year period, 2007-2008 and 2011.[128] Endo paid FSMB $371,620 over a 5 year period.[129] Mallinckrodt paid FSMB $100,000 in 2011.[130]

d. The Alliance for Patient Access

342. Founded in 2006, the Alliance for Patient Access ("APA") is a self-described patient advocacy and health professional organization that styles itself as "a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care."[131] It is run by Woodberry Associates LLC, a lobbying firm that was also established in 2006.[132] As of June 2017, the APA listed 30 "Associate Members and Financial Supporters." The list includes J&J, Endo, Mallinckrodt, Purdue, and Cephalon.

343. APA's board members have also directly received substantial funding from pharmaceutical companies.[133] For instance, board vice president Dr. Srinivas Nalamachu ("Nalamachu"), who practices in Kansas, received more than $800,000 from 2013 through 2015 from pharmaceutical companies—nearly all of it from manufacturers of opioids or drugs that treat

[127] Letter from Humayun J. Chaudhry, President and CEO, FSMB, to the Hon. Max Baucus and Hon. Charles Grassley, U.S. Senate (June 8, 2012), https://www.documentcloud.org/documents/3109089-FSMB-Response-Letter-to-US-Senate.html.
[128] *Id.*
[129] *Id.*
[130] *Id.*
[131] The Alliance for Patient Access, *About AfPA*, http://allianceforpatientaccess.org/about-afpa/#membership (last accessed August 1, 2018). References herein to APA include two affiliated groups: the Global Alliance for Patient Access and the Institute for Patient Access.
[132] Mary Chris Jaklevic, *Non-profit Alliance for Patient Access uses journalists and politicians to push Big Pharma's agenda*, Health News Review (Oct. 2, 2017), https://www.healthnewsreview.org/2017/10/non-profit-alliance-patient-access-uses-journalists-politicians-push-big-pharmas-agenda/ ("Jaklevic, *Non-profit Alliance for Patient Access*").
[133] All information concerning pharmaceutical company payments to doctors in this paragraph is from ProPublica's Dollars for Docs database, *available at* https://projects.propublica.org/docdollars/.

opioids' side effects, including from defendants Endo, Insys, Purdue and Cephalon. Nalamachu's clinic was raided by FBI agents in connection with an investigation of Insys and its payment of kickbacks to physicians who prescribed Subsys.[134] Other board members include Dr. Robert A. Yapundich from North Carolina, who received $215,000 from 2013 through 2015 from pharmaceutical companies, including payments by defendants Cephalon and Mallinckrodt; Dr. Jack D. Schim from California, who received more than $240,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Mallinckrodt and Cephalon; Dr. Howard Hoffberg from Maryland, who received $153,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Purdue, Insys, Mallinckrodt and Cephalon; and Dr. Robin K. Dore from California, who received $700,000 between 2013 and 2015 from pharmaceutical companies.

344. Among its activities, APA issued a "white paper" titled "*Prescription Pain Medication: Preserving Patient Access While Curbing Abuse.*"[135] Among other things, the white paper criticizes prescription monitoring programs, purporting to express concern that they are burdensome, not user friendly, and of questionable efficacy:

345. Prescription monitoring programs that are difficult to use and cumbersome can place substantial burdens on physicians and their staff, ultimately leading many to stop prescribing pain medications altogether. This forces patients to seek pain relief medications elsewhere, which may be much less convenient and familiar and may even be dangerous or illegal…. In some states,

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[134] Andy Marso, *FBI seizes records of Overland Park pain doctor tied to Insys*, KANSAS CITY STAR (July 19, 2017), http://www.kansascity.com/news/business/health-care/article162569383.html.

[135] Institute for Patient Access, *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse*, (Oct. 2013), http://1yh21u3cjptv3xjder1dco9mx5s.wpengine.netdna-cdn.com/wp-content/uploads/2013/01/PT_White-Paper_Finala.pdf.

physicians who fail to consult prescription monitoring databases before prescribing pain medications for their patients are subject to fines; those who repeatedly fail to consult the databases face loss of their professional licensure. Such penalties seem excessive and may inadvertently target older physicians in rural areas who may not be facile with computers and may not have the requisite office staff. Moreover, threatening and fining physicians in an attempt to induce compliance with prescription monitoring programs represents a system based on punishment as opposed to incentives ... We cannot merely assume that these programs will reduce prescription pain medication use and abuse.[136]

346. The white paper also purports to express concern about policies that have been enacted in response to the prevalence of pill mills:

> Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations, must have a Board certified medical director, may need to pay for annual inspections, and are subject to increased record keeping and reporting requirements. . . . [I]t is not even certain that the regulations are helping prevent abuses.[137]

347. In addition, in an echo of earlier industry efforts to push back against what they termed "opiophobia," the white paper laments the stigma associated with prescribing and taking pain medication: "Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can't get their prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong – or even criminal.... Physicians can face similar stigma from peers. Physicians in non-pain specialty areas often look down on those who specialize in pain management – a situation fueled by the numerous regulations and

[136] *Id*. at 4-5 (footnote omitted).
[137] *Id.* at 5-6.

fines that surround prescription pain medications."[138]

348. In conclusion, the white paper states that "[p]rescription pain medications, and specifically opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs."[139]

349. The APA also issues "Patient Access Champion" financial awards to members of Congress, including 50 such awards in 2015. The awards were funded by a $7.8 million donation from unnamed donors. While the awards are ostensibly given for protecting patients' access to Medicare and are thus touted by their recipients as demonstrating a commitment to protecting the rights of senior citizens and the middle class, they were generally given to members of Congress who supported the APA's agenda.[140]

350. The APA also lobbies Congress directly. In 2015, the APA signed onto a letter supporting legislation proposed to limit the ability of the DEA to police pill mills by enforcing the "suspicious orders" provision of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801, et seq. ("CSA" or "Controlled Substances Act").[141] The AAPM is also a signatory to this letter. An internal DOJ memo stated that the proposed bill "'could actually result in increased diversion, abuse, and public health and safety consequences'"[142] and, according to DEA chief administrative law judge John J. Mulrooney ("Mulrooney"), the law would make it "all

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[138] *Id.* at 6.
[139] *Id.* at 7.
[140] Jaklevic*, Non-profit Alliance for Patient Access*, *supra* n. 149.
[141] Letter from Alliance for Patient Access, et al., to Congressmen Tom Marino, Marsha Blackburn, Peter Welch, and Judy Chu (Jan. 26, 2015).
[142] Bill Whitaker, *Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and Congress*, CBS NEWS (last updated Oct. 17, 2017) https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress/ (hereinafter, "Whitaker, Opioid Crisis Fueled by Drug Industry").

but logically impossible" to prosecute manufacturers and distributors, like the defendants here, in the courts.[143] The law passed both Houses of Congress and was signed into law in 2016.

e. The U.S. Pain Foundation

351. The U.S. Pain Foundation ("USPF") was another Front Group with systematic connections and interpersonal relationships with the Marketing Defendants. The USPF was one of the largest recipients of contributions from the Marketing Defendants, collecting nearly $3 million in payments between 2012 and 2015 alone.[144] The USPF was also a critical component of the Marketing Defendants' lobbying efforts to reduce the limits on over-prescription. The U.S. Pain Foundation advertised its ties to the Marketing Defendants, listing opioid manufacturers like Pfizer, Teva, Depomed, Endo, Purdue, McNeil (i.e. Janssen), and Mallinckrodt as "Platinum," "Gold," and "Basic" corporate members.[145] Industry Front Groups like the American Academy of Pain Management, the American Academy of Pain Medicine, the American Pain Society, and PhRMA are also members of varying levels in the USPF.

352. More specifically, Purdue paid $359,300 from 2012-2017;[146] Janssen paid $41,500 from 2012-2017;[147] and Insys paid $2,500,000 from 2012-2017 to the USPF.[148]

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[143] John J. Mulrooney, II & Katherine E. Legel, *Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters*, 101 Marquette L. Rev. (forthcoming Feb. 2018), https://www.documentcloud.org/documents/4108121-Marquette-Law-Review-Mulrooney-Legel.html.
[144] *Fueling an Epidemic*, at p. 4.
[145] *Id*. at 12; U.S. Pain Foundation, *Transparency*, https://uspainfoundation.org/transparency/. (last accessed on August 1, 2018).
[145] *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc'y 1331 (2009), https://www.ncbi.nlm.nih.gov/pubmed/19573219 (last accessed on August 1, 2018).
[146] *Id.*
[147] *Id.*
[148] *Id.*

f. American Geriatrics Society

353. The AGS was another Front Group with systematic connections and interpersonal relationships with the Marketing Defendants. The AGS was a large recipient of contributions from the Marketing Defendants, including Endo, Purdue and Janssen. AGS contracted with Purdue, Endo, and Janssen to disseminate guidelines regarding the use of opioids for chronic pain in 2002 (*The Management of Persistent Pain in Older Persons*, hereinafter "2002 AGS Guidelines") and 2009 (*Pharmacological Management of Persistent Pain in Older Persons*,[149] hereinafter "2009 AGS Guidelines"). According to news reports, AGS has received at least $344,000 in funding from opioid manufacturers since 2009.[150] AGS's complicity in the common purpose with the Marketing Defendants is evidenced by the fact that AGS internal discussions in August 2009 reveal that it did not want to receive up front funding from drug companies, which would suggest drug company influence, but would instead accept commercial support to disseminate pro-opioid publications.

354. More specifically, Purdue paid $11,785 from 2012-2017[151] and provided $40,000 in "corporate roundtable dues" to AGS's Health in Aging Foundation, a 501(c)(3) organization affiliated with the group between 2012 and 2015.[152]

355. The 2009 AGS Guidelines recommended that "[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy." The panel made "strong

[149] *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc'y 1331 (2009), https://www.ncbi.nlm.nih.gov/pubmed/19573219 (last accessed on August 1, 2018).
[150] John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, MILWAUKEE J. SENTINEL (May 30, 2012), https://www.medpagetoday.com/geriatrics/painmanagement/32967.
[151] *Fueling an Epidemic Part Two*.
[152] Letter from Nancy E. Lundebjerg, Chief Executive Office, American Geriatrics Society, to Sen. Claire McCaskill (Oct. 11, 2017).

recommendations" in this regard despite "low quality of evidence" and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse.[153] These Guidelines further recommended that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." These recommendations are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited over 500 times in Google Scholar (which allows users to search scholarly publications that would be have been relied on by researchers and prescribers) since their 2009 publication and as recently as this year.

356. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions that drug companies, including Purdue, Endo, Janssen, and Teva, made to the sponsoring organizations and committee members.

357. Dr. Bruce Farrell was an AGS task force chairman for the 2009 Guidelines, but was also a paid speaker for Endo, and he helped conduct a CME for treating osteoarthritis pain, which was funded by Purdue.[154]

358. Representatives of the Marketing Defendants, often at informal meetings at conferences, suggested activities, lobbying efforts and publications for AGS to pursue. AGS then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

359. Members of AGS Board of Directors were doctors who were on the Marketing Defendants' payrolls, either as consultants or as speakers for medical events. As described below,

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[153] 2009 AGS Guidelines at 1342.

[154] John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, MILWAUKEE J. SENTINEL (May 30, 2012), https://www.medpagetoday.com/geriatrics/painmanagement/32967.

many of the KOLs also served in leadership positions within the AGS.

g. American Chronic Pain Association

360. The Manufacturer Defendants also made substantial payments to the American Chronic Pain Association ("ACPA"). Founded in 1980, the ACPA offers support and education for people suffering with chronic pain.

361. Contributions to the ACPA from the Manufacturing Defendants include $312,470 from Purdue and $50,000 from Janssen from 2012-2017.[155] Between 2013 and 2016, 10 members of ACPA's Advisory Board received more than $140,000 from opioid manufacturers, including Endo.

4. The Marketing Defendants Deceptively Paid Key Opinion Leaders to Promote Opioid Use

362. To falsely promote their opioids, the Marketing Defendants paid and cultivated a select circle of doctors who were chosen and sponsored by the Marketing Defendants for their supportive messages. As set forth below, pro-opioid doctors have been at the hub of the Marketing Defendants' well-funded, pervasive marketing scheme since its inception and were used to create the grave misperception that science and legitimate medical professionals favored the wider and broader use of opioids. These doctors include Dr. Russell Portenoy, Dr. Lynn Webster, Dr. Perry Fine, and Dr. Scott Fishman.

363. Although these KOLs were funded by the Marketing Defendants, the KOLs were used extensively to present the appearance that unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain had been conducted and was being reported on by independent medical professionals.

364. As the Marketing Defendants' false marketing scheme picked up steam, these pro-

[155] *Fueling an Epidemic Part Two.*

opioid KOLs wrote, consulted on, edited, and lent their names to books and articles, and gave speeches and CMEs supportive of opioid therapy for chronic pain. They served on committees that developed treatment guidelines that strongly encouraged the use of opioids to treat chronic pain and they were placed on boards of pro-opioid advocacy groups and professional societies that developed, selected, and presented CMEs.

365. Through use of their KOLs and strategic placement of these KOLs throughout every critical distribution channel of information within the medical community, the Marketing Defendants were able to exert control of each of these modalities through which doctors receive their information.

366. In return for their pro-opioid advocacy, the Marketing Defendants' KOLs received money, prestige, recognition, research funding, and avenues to publish. For example, Dr. Webster has received funding from Endo, Purdue, and Cephalon. Dr. Fine has received funding from Janssen, Cephalon, Endo, and Purdue.

367. The Marketing Defendants carefully vetted their KOLs to ensure that they were likely to remain on-message and supportive of the Marketing Defendants' agenda. The Marketing Defendants also kept close tabs on the content of the materials published by these KOLs. Of course, the Marketing Defendants also kept these KOLs well-funded, enabling them to push the Marketing Defendants' deceptive message out to the medical community.

368. Once the Marketing Defendants identified and funded KOLs and those KOLs began to publish "scientific" papers supporting the Marketing Defendants' false position that opioids were safe and effective for treatment of chronic pain, the Marketing Defendants poured significant funds and resources into a marketing machine that widely cited and promoted their KOLs and studies or articles by their KOLs to drive prescriptions of opioids for chronic pain. The Marketing

Defendants cited to, distributed, and marketed these studies and articles by their KOLs as if they were independent medical literature so that it would be well-received by the medical community. By contrast, the Marketing Defendants did not support, acknowledge, or disseminate the truly independent publications of doctors critical of the use of chronic opioid therapy.

369. In their promotion of the use of opioids to treat chronic pain, the Marketing Defendants' KOLs knew that their statements were false and misleading, or they recklessly disregarded the truth in doing so, but they continued to publish their misstatements to benefit themselves and the Marketing Defendants.

a. Dr. Russell Portenoy

370. In 1986, Dr. Russell Portenoy, who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York while at the same time serving as a top spokesperson for drug companies, published an article reporting that "[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy."[156]

371. Writing in 1994, Dr. Portenoy described the prevailing attitudes regarding the dangers of long-term use of opioids:

372. *The traditional approach to chronic non-malignant pain does not accept the long-term administration of opioid drugs.* This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood

[156] Russell Portenoy & Kathy Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases*, 25(2) Pain 171 (1986), https://www.ncbi.nlm.nih.gov/pubmed/2873550.

changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. *Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.*[157]

373. (emphasis added). According to Dr. Portenoy, the foregoing problems could constitute "compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain."[158]

374. Despite having taken this position on long-term opioid treatment, Dr. Portenoy ended up becoming a spokesperson for Purdue and other Marketing Defendants, promoting the use of prescription opioids and minimizing their risks. A respected leader in the field of pain treatment, Dr. Portenoy was highly influential. Dr. Andrew Kolodny, cofounder of Physicians for Responsible Opioid Prescribing, described him "lecturing around the country as a religious-like figure. The megaphone for Portenoy is Purdue, which flies in people to resorts to hear him speak. It was a compelling message: 'Docs have been letting patients suffer; nobody really gets addicted; it's been studied.'"[159]

375. As one organizer of CME seminars who worked with Portenoy and Purdue pointed out, "had Portenoy not had Purdue's money behind him, he would have published some papers,

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[157] Russell Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994) (emphasis added).
[158] *Id.*
[159] *Dreamland* at 314.

made some speeches, and his influence would have been minor. With Purdue's millions behind him, his message, which dovetailed with their marketing plans, was hugely magnified."[160]

376. Dr. Portenoy was also a critical component of the Marketing Defendants' control over their Front Groups. Specifically, Dr. Portenoy sat as a Director on the board of the APF. He was also the President of the APS.

377. In recent years, some of the Marketing Defendants' KOLs have conceded that many of their past claims in support of opioid use lacked evidence or support in the scientific literature.[161] Dr. Portenoy has now admitted that he minimized the risks of opioids,[162] and that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true."[163] He mused, "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did . . ."[164]

378. In a 2011 interview released by Physicians for Responsible Opioid Prescribing, Portenoy stated that his earlier work purposefully relied on evidence that was not "real" and left real evidence behind:

379. I gave so many lectures to primary care audiences in which the Porter and Jick article was just one piece of data that I would then cite, and I would cite six, seven, maybe ten

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[160] *Id.* at 136.
[161] *See*, *e.g.*, John Fauber, *Painkiller boom fueled by networking*, Journal Sentinel (Feb. 18, 2012), http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html/ (reporting that a key Endo KOL acknowledged that opioid marketing went too far).
[162] Celine Gounder, *Who Is Responsible for the Pain-Pill Epidemic?*, THE NEW YORKER (Nov. 8, 2013), https://www.newyorker.com/business/currency/who-is-responsible-for-the-pain-pill-epidemic (hereinafter "Gounder, *Who Is Responsible*").
[163] Thomas Catan and Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, THE WALL STREET JOURNAL (Dec. 17, 2012), https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.
[164] *Id*.

different avenues of thought or avenues of evidence, *none of which represented real evidence*, and yet what I was trying to do was to create a narrative so that the primary care audience would look at this information in [total] and feel more comfortable about opioids in a way they hadn't before. *In essence this was education to destigmatize [opioids], and because the primary goal was to destigmatize, we often left evidence behind.*[165]

380. Several years earlier, when interviewed by journalist Barry Meier for his 2003 book, *Pain Killer*, Dr. Portenoy was more direct: "It was pseudoscience. I guess I'm going to have always to live with that one."[166]

b. Dr. Lynn Webster

381. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of the Lifetree Clinical Research & Pain Clinic in Salt Lake City, Utah. Dr. Webster was President in 2013 and is a current board member of AAPM, a Front Group that ardently supports chronic opioid therapy. He is a Senior Editor of Pain Medicine, the same journal that published Endo's special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Defendants (including nearly $2 million from Cephalon).

382. Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe

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[165] Harrison Jacobs, *This one-paragraph letter may have launched the opioid epidemic*, BUSINESS INSIDER (May 26, 2016), http://www.businessinsider.com/porter-and-jick-letter-launched-the-opioid-epidemic-2016-5; Andrew Kolodny, *Opioids for Chronic Pain: Addiction is NOT Rare*, YouTube (Oct. 30, 2011), https://www.youtube.com/watch?v=DgyuBWN9D4w&feature=youtu.be.

[166] *Pain Killer*, *supra* n. 63, at 277.

opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool ("ORT") appear on, or are linked to, websites run by Endo, Janssen, and Purdue. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patient's Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach doctors in Kentucky.

383. Dr. Webster was himself tied to numerous overdose deaths. He and the Lifetree Clinic were investigated by the DEA for overprescribing opioids after twenty patients died from overdoses. In keeping with the Marketing Defendants' promotional messages, Dr. Webster apparently believed the solution to patients' tolerance or addictive behaviors was more opioids: he prescribed staggering quantities of pills.

384. At an AAPM annual meeting held February 22 through 25, 2006, Cephalon sponsored a presentation by Webster and others titled, "Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: Interim safety results." The presentation's agenda description states: "Most patients with chronic pain experience episodes of breakthrough pain, yet no currently available pharmacologic agent is ideal for its treatment." The presentation purports to cover a study analyzing the safety of a new form of fentanyl buccal tablets in the chronic pain setting and promises to show the "[i]nterim results of this study suggest that [fentanyl buccal] is safe and well-tolerated in patients with chronic pain and [breakthrough pain]." This CME effectively amounted to off-label promotion of Cephalon's opioids, even though they were approved only for cancer pain.

385. Cephalon sponsored a CME written by Dr. Webster, *Optimizing Opioid Treatment*

for Breakthrough Pain, offered by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating breakthrough pain because of dose limitations on the non-opioid component.

c. Dr. Perry Fine

386. Dr. Perry Fine's ties to the Marketing Defendants have been well documented. He has authored articles and testified in court cases and before state and federal committees, and he, too, has argued against legislation restricting high-dose opioid prescription for non-cancer patients. He has served on Purdue's advisory board, provided medical legal consulting for Janssen, and participated in CME activities for Endo, along with serving in these capacities for several other drug companies. He co-chaired the APS-AAPM Opioid Guideline Panel, served as treasurer of the AAPM from 2007 to 2010 and as president of that group from 2011 to 2013, and was also on the board of directors of APF.[167]

387. Multiple videos feature Fine delivering educational talks about prescription opioids. He even testified at trial that the 1,500 pills a month prescribed to celebrity Anna Nicole Smith before her death for pain did not make her an addict.

388. Dr. Fine has also acknowledged having failed to disclose numerous conflicts of interest. For example, Dr. Fine failed to fully disclose payments received as required by his employer, the University of Utah—telling the university that he had received under $5,000 in 2010 from Johnson & Johnson for providing "educational" services, but Johnson & Johnson's website

[167] Scott M. Fishman, MD, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, 306 (13) JAMA 1445 (Sept. 20, 2011), https://jamanetwork.com/journals/jama/article-abstract/1104464?redirect=true.

states that the company paid him $32,017 that year for consulting, promotional talks, meals and travel .[168]

389. Dr. Fine and Dr. Portenoy co-wrote *A Clinical Guide to Opioid Analgesia* in which they downplayed the risks of opioid treatment such as respiratory depression and addiction: "At clinically appropriate doses . . . respiratory rate typically does not decline. Tolerance to the respiratory effects usually develops quickly, and doses can be steadily increased without risk. Overall, the literature provides evidence that the outcomes of drug abuse and addiction are rare among patients who receive opioids for a short period (i.e., for acute pain) and among those with no history of abuse who receive long-term therapy for medical indications.[169]

390. In November 2010, Dr. Fine and others published an article presenting the results of another Cephalon-sponsored study titled "Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study."[170] In that article, Dr. Fine explained that the 18-month "open-label" study "assessed the safety and tolerability of FBT [Fentora] for the [long-term] treatment of BTP in a large cohort . . . of opioid-tolerant patients receiving around-the-clock . . . opioids for non-cancer pain."[171] The article acknowledged that: (a) "[t]here has been a steady increase in the use of opioids for the management of chronic non-cancer pain over the past two decades"; (b) the

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[168] Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011), https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry.

[169] Perry G. Fine, MD and Russell K. Portenoy, MD, *A Clinical Guide to Opioid Analgesia* 20 and 34, McGraw-Hill Companies (2004), http://www.thblack.com/links/RSD/OpioidHandbook.pdf.

[170] Perry G. Fine, et al., *Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study*, 40(5) J. Pain & Symptom Management 747-60 (Nov. 2010).

[171] *Id.*

"widespread acceptance" had led to the publishing of practice guidelines "to provide evidence- and consensus-based recommendations for the optimal use of opioids in the management of chronic pain"; and (c) those guidelines lacked "data assessing the long-term benefits and harms of opioid therapy for chronic pain."[172]

391. The article concluded: "[T]he safety and tolerability profile of FBT in this study was generally typical of a potent opioid. The [adverse events] observed were, in most cases, predictable, manageable, and tolerable." They also conclude that the number of abuse-related events was "small."[173]

392. Multiple videos feature Dr. Fine delivering educational talks about the drugs. In one video from 2011 titled "Optimizing Opioid Therapy," he sets forth a "Guideline for Chronic Opioid Therapy" discussing "opioid rotation" (switching from one opioid to another) not only for cancer patients, but also for non-cancer patients, and suggests it may take four or five switches over a person's "lifetime" to manage pain.[174] He states the "goal is to improve effectiveness which is different from efficacy and safety." Rather, for chronic pain patients, effectiveness "is a balance of therapeutic good and adverse events *over the course of years*."[175] The entire program assumes that opioids are appropriate treatment over a "protracted period of time" and even over a patient's entire "lifetime." He even suggests that opioids can be used to treat *sleep apnea*. He further states that the associated risks of addiction and abuse can be managed by doctors and evaluated with "tools," but leaves that for "a whole other lecture."[176]

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[172] *Id.*
[173] *Id.*
[174] Perry A. Fine, M.D., *Safe and Effective Opioid Rotation*, YouTube.com (Nov. 8, 2012), https://www.youtube.com/watch?v=_G3II9yqgXI.
[175] *Id.*
[176] *Id.*

d. Dr. Scott Fishman

393. Dr. Scott Fishman is a physician whose ties to the opioid drug industry are multitudinous. He has served as an APF board member and as president of the AAPM and has participated yearly in numerous CME activities for which he received "market rate honoraria." As discussed below, he has authored publications, including the seminal guides on opioid prescribing, which were funded by the Marketing Defendants. He has also worked to oppose legislation requiring doctors and others to consult pain specialists before prescribing high doses of opioids to non-cancer patients. He has himself acknowledged his failure to disclose all potential conflicts of interest in a letter in the *Journal of the American Medical Association* titled "Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion."[177]

394. Dr. Fishman authored a physician's guide on the use of opioids to treat chronic pain titled "Responsible Opioid Prescribing," in 2007 which promoted the notion that long-term opioid treatment was a viable and safe option for treating chronic pain.

395. In 2012, Dr. Fishman updated the guide and continued emphasizing the "catastrophic" "under-treatment" of pain and the "crisis" such under-treatment created: "Given the magnitude of the problems related to opioid analgesics, it can be tempting to resort to draconian solutions: clinicians may simply stop prescribing opioids, or legislation intended to improve pharmacovigilance may inadvertently curtail patient access to care. As we work to reduce diversion and misuse of prescription opioids, it's critical to remember that the problem of

[177] Scott M. Fishman, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, 306(13) JAMA 1445 (2011); Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011), https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry (hereinafter "Weber, *Two Leaders in Pain*").

unrelieved pain remains as urgent as ever."[178]

396. The updated guide still assures that "[o]pioid therapy to relieve pain and improve function is legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins."[179]

397. In another guide by Dr. Fishman, he continues to downplay the risk of addiction: "I believe clinicians must be very careful with the label 'addict.' I draw a distinction between a 'chemical coper' and an addict."[180] The guide also continues to present symptoms of addiction as symptoms of "pseudoaddiction."

5. The Marketing Defendants Also Spread Their Misleading Messages to Reputable Organizations

398. The Manufacturing Defendants also manipulated reputable organizations like the Joint Commission on Accreditation of Healthcare Organizations (the "Joint Commission") in order to further advance their unlawful marketing of opioids. The Joint Commission certifies over 21,000 health care organizations and is the nation's oldest and largest standards-setting and accrediting body in health care.[181]

399. In 2000, Purdue sponsored a book through the Joint Commission which claimed "there is no evidence that addiction is a significant issue when persons are given opioids for pain control."[182] It also called doctors' concerns about addiction side effects "inaccurate and

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[178] Scott M. Fishman, *Responsible Opioid Prescribing: A Guide for Michigan Clinicians*, 10-11 (Waterford Life Sciences 2012).
[179] *Id.*
[180] Scott M. Fishman, *Listening to Pain: A Physician's Guide to Improving Pain Management Through Better Communication* 45 (Oxford University Press 2012).
[181] Joint Commission, *FAQ Page*, *available at* https://www.jointcommission.org/about/jointcommissionfaqs.aspx?CategoryId=10#2274 (last accessed August 1, 2018).
[182] Sonia Moghe, *Opioid history: From 'wonder drug' to abuse epidemic*, CNN (Oct. 13, 2016), https://www.cnn.com/2016/05/12/health/opioid-addiction-history/.

exaggerated."[183] Dr. David W. Baker, the Joint Commission's executive vice president for health care quality evaluation, has acknowledged that "[t]he Joint Commission was one of the dozens of individual authors and organizations that developed educational materials for pain management that propagated this erroneous information."[184]

400. In 2001, due to the influence of the Marketing Defendants, the Joint Commission, along with the National Pharmaceutical Council (founded in 1953 and supported by the nation's major research-based biopharmaceutical companies[185]) "introduced standards for [hospitals] to improve their care for patients with pain." The new standards for hospitals put patient pain front and center as the "fifth vital sign." This monograph, entitled *Pain: Current Understanding of Assessment, Management and Treatments* required assessment of pain in all patients.

401. The Joint Commission's first pain management standards placed responsibility for pain control on health care organizations (hospitals), and emphasized the need for hospitals to do systematic assessments and use quantitative measures of pain which was consistent with the position of the Front Group APS.

402. As a result of the Marketing Defendants' efforts to manipulate the standard of care, many hospitals risked loss of their Joint Commission accreditation if they did not incorporate the "fifth vital sign" standard and put pain at the forefront of their treatment. For example, the emergency department at Oconomowoc Memorial Hospital in Wisconsin achieved 10 consecutive years of patient satisfaction in the 99th percentile, a feat no other emergency hospital in the United States has been able to accomplish.[186] However, during its routine Joint Commission survey, The

[183] *Id.*
[184] *Id.*
[185] Currently funded by Johnson & Johnson, Purdue and Teva, among others.
[186] Westlake testimony, at 6.

Joint Commission found that the hospital was not adequately documenting follow up questions after prescribing pain medications to patients.[187] As a result, the hospital was given only one quarter to bring their compliance up to 90%.[188] They could not, and as a result their Joint Commission accreditation was at risk for the entire hospital.[189] Loss of accreditation by The Joint Commission can result in the loss of a huge amount of hospital resources to become reaccredited, despite having a patient satisfaction rating of 99% for the same period.[190]

403. Since 2001, The Joint Commission standards relating to pain assessment and management have been revised to lessen emphasis on pain. However, the damage caused by the Marketing Defendants' marketing campaigns could not be undone. Dr. Baker explains that "the concept that iatrogenic addiction was rare and that long acting opioids were less addictive had been greatly reinforced and widely repeated, and studies refuting these claims were not published until several years later."

6. The Marketing Defendants Disseminated Their Misrepresentations Through Continuing Medical Education Programs

404. Now that the Marketing Defendants had both a group of physician promoters and had built a false body of "literature," Defendants needed to make sure their false marketing message was widely distributed.

405. One way the Marketing Defendants aggressively distributed their false message was through countless CME programs.

406. Doctors are required to attend a certain number and, often, type of CME programs each year as a condition of their licensure. These programs are generally delivered in person, often

[187] *Id.*
[188] *Id.*
[189] *Id.*
[190] *Id.*

in connection with professional organizations' conferences, online, or through written publications. Doctors rely on CMEs not only to satisfy licensing requirements, but also to get information on new developments in medicine or to deepen their knowledge in specific areas of practice. Because CMEs typically are taught by KOLs who are highly respected in their fields, and are thought to reflect these physicians' medical expertise, they can be especially influential with doctors.

407. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. As one target, Defendants aimed to reach general practitioners, whose broad area of practice and lack of expertise and specialized training in pain management made them particularly dependent upon CMEs and, as a result, especially susceptible to the Marketing Defendants' deceptions.

408. The Marketing Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focused on opioids to the exclusion of alternative treatments, inflated the benefits of opioids, and frequently omitted or downplayed their risks and adverse effects.

409. Cephalon sponsored numerous CME programs, which were made widely available through organizations like Medscape, LLC ("Medscape") and which disseminated false and misleading information to physicians across the country.

410. Another Cephalon-sponsored CME presentation titled *Breakthrough Pain*: *Treatment Rationale with Opioids* was available on Medscape starting September 16, 2003 and was given by a self-professed pain management doctor who "previously operated back, complex

pain syndromes, the neuropathies, and interstitial cystitis." He describes the pain process as a non-time-dependent continuum that requires a balanced analgesia approach using "targeted pharmaco therapeutics to affect multiple points in the pain-signaling pathway."[191] The doctor lists fentanyl as one of the most effective opioids available for treating breakthrough pain, describing its use as an expected and normal part of the pain management process.[192] Nowhere in the CME is cancer or cancer-related pain even mentioned, despite FDA restrictions that fentanyl use be limited to cancer-related pain.

411. Teva paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or non-cancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

412. *Responsible Opioid Prescribing* was sponsored by Purdue, Endo and Teva. The FSMB website described it as the "leading continuing medical education (CME) activity for prescribers of opioid medications." Endo sales representatives distributed copies of *Responsible Opioid Prescribing* with a special introductory letter from Dr. Scott Fishman.

413. In all, more than 163,000 copies of *Responsible Opioid Prescribing* were distributed nationally.

414. The American Medical Association ("AMA") recognized the impropriety that pharmaceutical company-funded CMEs create, stating that support from drug companies with a financial interest in the content being promoted "creates conditions in which external interests

[191] Daniel S. Bennett, *Breakthrough Pain: Treatment Rationale With Opioids*, Medscape, http://www.medscape.org/viewarticle/461612 (last accessed August 1, 2018).
[192] *Id.*

could influence the availability and/or content" of the programs and urged that "[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the education subject matter."[193]

415. Physicians attended or reviewed CMEs sponsored by the Marketing Defendants during the relevant time period and were misled by them.

416. By sponsoring CME programs put on by Front Groups like APF, AAPM, and others, the Marketing Defendants expected and understood that instructors would deliver messages favorable to them, as these organizations were dependent on the Marketing Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Marketing Defendant-driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids. Producers of CMEs and the Marketing Defendants both measure the effects of CMEs on prescribers' views on opioids and their absorption of specific messages, confirming the strategic marketing purpose in supporting them.

7. The Marketing Defendants Used "Branded" Advertising to Promote Their Products to Doctors and Consumers

417. The Marketing Defendants engaged in widespread advertising campaigns touting the benefits of their branded drugs. The Marketing Defendants published print advertisements in a broad array of medical journals, ranging from those aimed at specialists, such as the Journal of Pain and Clinical Journal of Pain, to journals with wider medical audiences, such as the Journal of the American Medical Association. The Marketing Defendants collectively spent more than $14

[193] Opinion 9.0115, *Financial Relationships with Industry in CME*, Am. Med. Ass'n (Nov. 2011).

million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. The 2011 total includes $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo.

418. The Marketing Defendants also targeted consumers in their advertising. They knew that physicians are more likely to prescribe a drug if a patient specifically requests it.[194] They also knew that this willingness to acquiesce to such patient requests holds true even for opioids and for conditions for which they are not approved.[195] Endo's research, for example, found that such communications resulted in greater patient "brand loyalty," with longer durations of Opana ER therapy and fewer discontinuations. The Marketing Defendants thus increasingly took their opioid sales campaigns directly to consumers, including through patient-focused "education and support" materials in the form of pamphlets, videos, or other publications that patients could view in their physician's office.

8. The Marketing Defendants Used "Unbranded" Advertising To Promote Opioid Use For Chronic Pain Without FDA Review

419. The Marketing Defendants also aggressively promoted opioids through "unbranded advertising" to generally tout the benefits of opioids without specifically naming a particular brand-name opioid drug. Instead, unbranded advertising is usually framed as "disease awareness"—encouraging consumers to "talk to your doctor" about a certain health condition without promoting a specific product and, therefore, without providing balanced disclosures about the product's limits and risks. In contrast, a pharmaceutical company's "branded" advertisement that identifies a specific medication and its indication (i.e., the condition which the drug is approved to treat) must also include possible side effects and contraindications—what the FDA

[194] In one study, for example, nearly 20% of sciatica patients requesting oxycodone received a prescription for it, compared with 1% of those making no specific request. J.B. McKinlay et al., *Effects of Patient Medication Requests on Physician Prescribing Behavior*, 52(2) Med. Care 294 (2014).
[195] *Id.*

Guidance on pharmaceutical advertising refers to as "fair balance." Branded advertising is also subject to FDA review for consistency with the drug's FDA-approved label. Through unbranded materials, the Marketing Defendants expanded the overall acceptance of and demand for chronic opioid therapy without the restrictions imposed by regulations on branded advertising.

420. Many of the Marketing Defendants utilized unbranded websites to promote opioid use without promoting a specific branded drug, such as Purdue's pain-management website, *www.inthefaceofpain.com*. The website contained testimonials from several dozen "advocates," including health care providers, urging more pain treatment. The website presented the advocates as neutral and unbiased, but an investigation by the New York Attorney General later revealed that Purdue paid the advocates hundreds of thousands of dollars.

9. The Marketing Defendants Funded, Edited And Distributed Publications That Supported Their Misrepresentations

421. The Marketing Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was calculated to shape the perceptions of prescribers, patients, and payors. This literature served marketing goals, rather than scientific standards, and was intended to persuade doctors and consumers that the benefits of long-term opioid use outweighed the risks.

422. To accomplish their goal, the Marketing Defendants—sometimes through third-party consultants and/or Front Groups—commissioned, edited, and arranged for the placement of favorable articles in academic journals.

423. The Marketing Defendants' plans for these materials did not originate in the departments with the organizations that were responsible for research, development, or any other area that would have specialized knowledge about the drugs and their effects on patients; rather,

they originated in the Marketing Defendants' marketing departments.

424. The Marketing Defendants made sure that favorable articles were disseminated and cited widely in the medical literature, even when the Marketing Defendants knew that the articles distorted the significance or meaning of the underlying study, as with the Porter & Jick letter. The Marketing Defendants also frequently relied on unpublished data or posters, neither of which are subject to peer review, but were presented as valid scientific evidence.

425. The Marketing Defendants published or commissioned deceptive review articles, letters to the editor, commentaries, case-study reports, and newsletters aimed at discrediting or suppressing negative information that contradicted their claims or raised concerns about chronic opioid therapy.

426. For example, in 2007 Cephalon sponsored the publication of an article titled "*Impact of Breakthrough Pain on Quality of Life in Patients with Chronic, Non-cancer Pain: Patient Perceptions and Effect of Treatment with Oral Transmucosal Fentanyl Citrate*,"[196] published in the nationally circulated Journal of Pain Medicine, to support its effort to expand the use of its branded fentanyl products. The article's authors (including Dr. Lynn Webster, discussed above) stated that the "OTFC [fentanyl] has been shown to relieve BTP [breakthrough pain] more rapidly than conventional oral, normal-release, or 'short acting' opioids" and that "[t]he purpose of [the] study was to provide a qualitative evaluation of the effect of BTP on the [quality of life] of non-cancer pain patients." The number-one-diagnosed cause of chronic pain in the patients studied was back pain (44%), followed by musculoskeletal pain (12%) and head pain (7%). The article cites Portenoy and recommends fentanyl for non-cancer BTP patients:

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[196] Donald R. Taylor, et al., *Impact of Breakthrough Pain on Quality of Life in Patients With Chronic, Non-cancer Pain: Patient Perceptions and Effect of Treatment With Oral Transmucosal Fentanyl Citrate (OTFC, ACTIQ)*, 8(3) Pain Med. 281-88 (Mar. 2007).

427. In summary, BTP appears to be a clinically important condition in patients with chronic non-cancer pain and is associated with an adverse impact on QoL. This qualitative study on the negative impact of BTP and the potential benefits of BTP-specific therapy suggests several domains that may be helpful in developing BTP-specific, QoL assessment tools.[197]

10. The Marketing Defendants Used "Detailers" To Directly Disseminate Their Misrepresentations To Prescribers

428. The Marketing Defendants' sales representatives executed carefully crafted marketing tactics, developed at the highest rungs of their corporate ladders, to reach targeted doctors and hospitals with centrally orchestrated messages. The Marketing Defendants' sales representatives also distributed third-party marketing material to their target audience that was deceptive.

429. Each Marketing Defendant promoted opioids through sales representatives (also called "detailers") and, in consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that small group speaker programs were designed to reach out to individual prescribers. By establishing close relationships with doctors, the Marketing Defendants were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to promote their opioids and to allay individual prescribers' concerns about prescribing opioids for chronic pain.

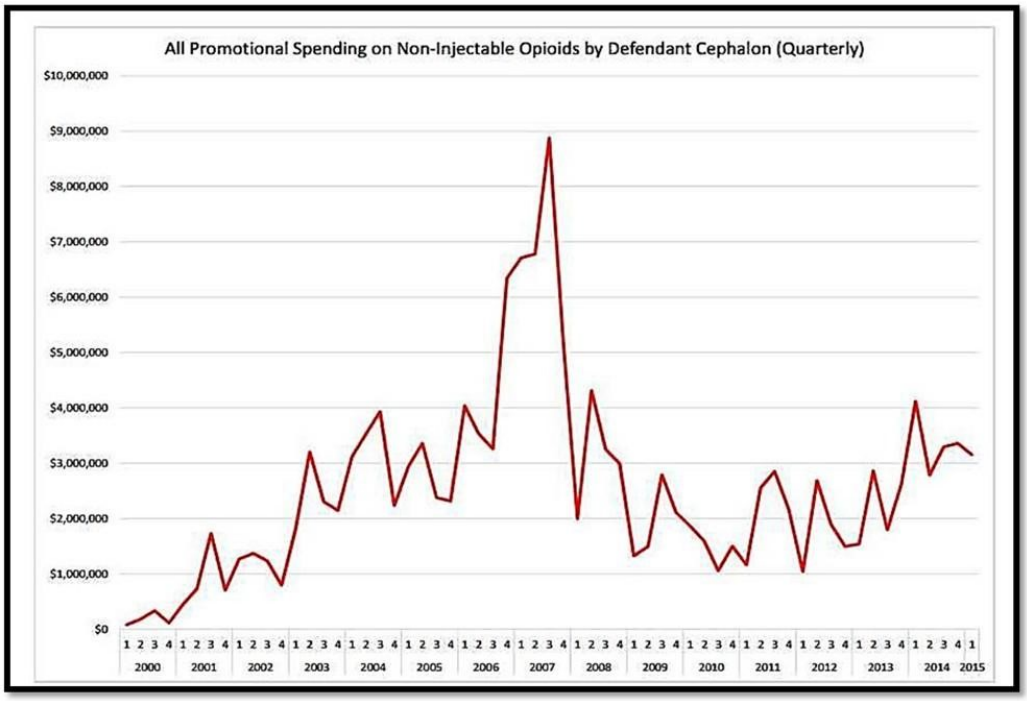
430. In accordance with common industry practice, the Marketing Defendants purchased and closely analyzed prescription sales data from IMS Health (now IQVIA), a healthcare data collection, management, and analytics corporation. This data allowed them to precisely track the rates of initial and renewal prescribing by individual doctors, which allowed them to target and

[197] *Id.*

tailor their appeals. Sales representatives visited hundreds of thousands of doctors and disseminated the misinformation and materials described above.

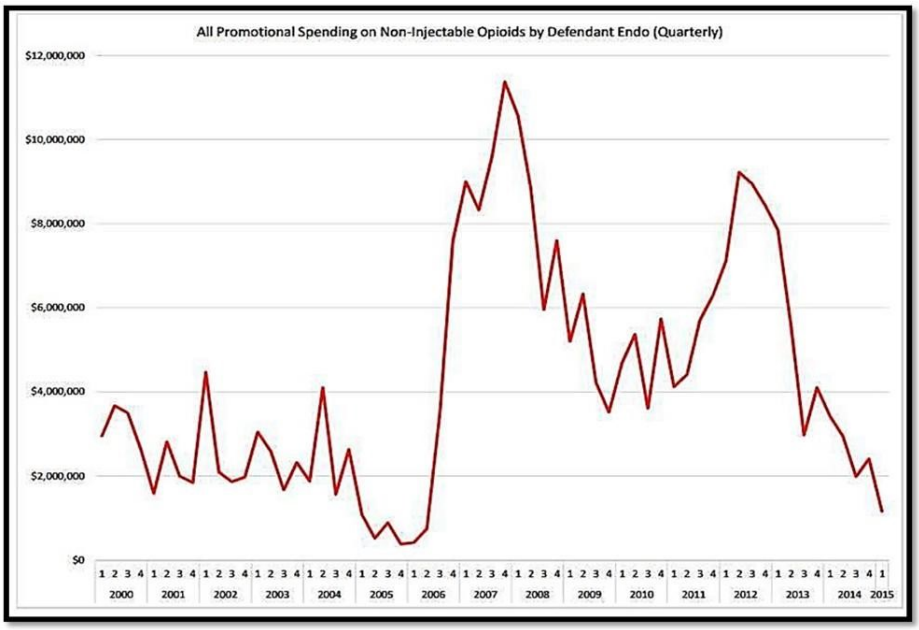
431. Marketing Defendants devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, Marketing Defendants spent $166 million on detailing branded opioids to doctors. This amount is twice as much as Marketing Defendants spent on detailing in 2000. The amount includes $108 million spent by Purdue, $34 million by Janssen, $13 million by Teva, and $10 million by Endo.

432. Cephalon's quarterly spending steadily climbed from below $1 million in 2000 to more than $3 million in 2014 (and more than $13 million for the year), with a peak, coinciding with the launch of Fentora, of more than $27 million in 2007, as shown below:

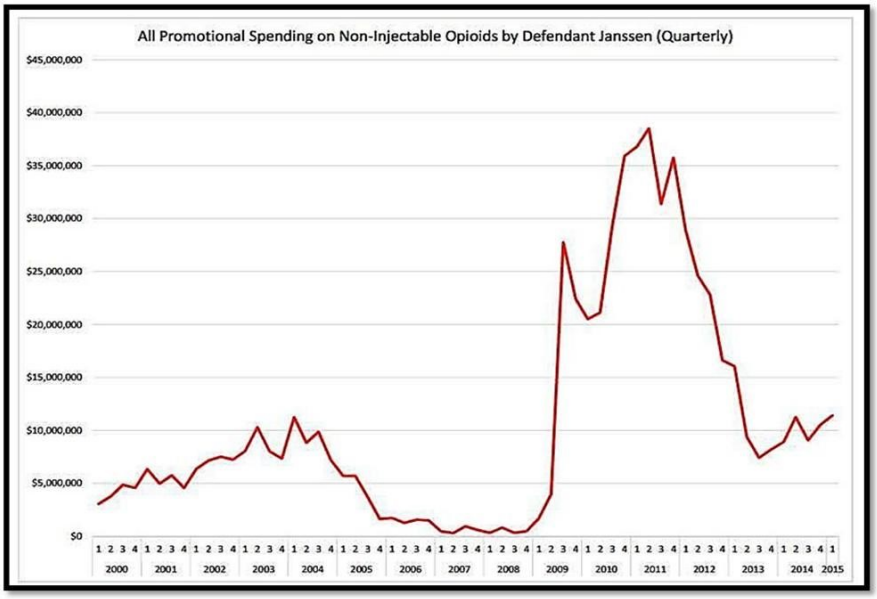


433. Endo's quarterly spending went from the $2 million to $4 million range in 2000-2004 to more than $10 million following the launch of Opana ER in mid-2006 (and more than $38 million for the year in 2007) and more than $8 million coinciding with the launch of a reformulated

version in 2012 (and nearly $34 million for the year), as shown below:

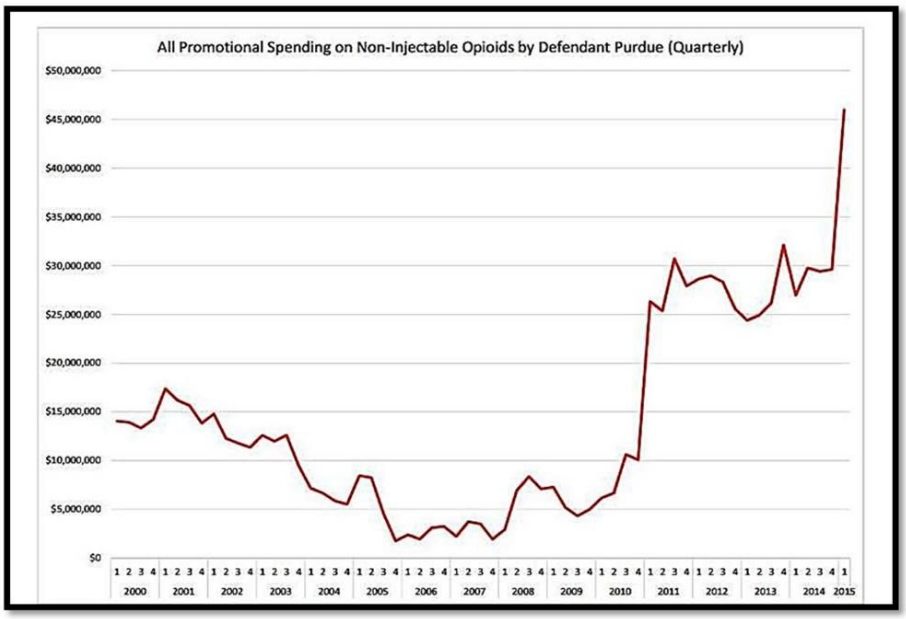


434. Janssen's quarterly spending dramatically rose from less than $5 million in 2000 to more than $30 million in 2011, coinciding with the launch of Nucynta ER (with yearly spending at $142 million for 2011), as shown below:



435. Purdue's quarterly spending notably decreased from 2000 to 2007, as Purdue came under investigation by the Department of Justice, but then spiked to above $25 million in 2011

(for a total of $110 million that year), and continues to rise, as shown below:



436. For its opioid, Actiq, Cephalon also engaged in direct marketing in direct contravention of the FDA's strict instructions that Actiq be prescribed only to terminal cancer patients and by oncologists and pain management doctors experienced in treating cancer pain.

11. The Marketing Defendants Used Speakers' Bureaus and Programs to Spread Their Deceptive Messages

437. In addition to making sales calls, the Marketing Defendants' detailers also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers with meals paid for by the Marketing Defendants. These speaker programs and associated speaker trainings served three purposes: they provided 1) an incentive to doctors to prescribe, or increase their prescriptions of, a particular drug; 2) an opportunity for doctors to be selected to attend forum at which the drug companies could further market to the speaker himself or herself; and 3) an opportunity for the doctors to market to their peers. The Marketing Defendants graded their speakers, and future opportunities were based on speaking performance, post-program sales, and product usage. Purdue, Janssen, Endo, Cephalon, and Mallinckrodt each made thousands of

payments to physicians nationwide, for activities including participating on speakers' bureaus, providing consulting services, and other services.

12. The Marketing Defendants Targeted Vulnerable Populations

438. The Marketing Defendants specifically targeted their marketing at two particularly vulnerable populations—the elderly and veterans – who tend to suffer from chronic pain.

439. The Marketing Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that existing evidence confirms that elderly patients taking opioids suffer from elevated fall and fracture risks, reduced renal function and medication clearance, and a smaller window between safe and unsafe dosages.[198] Elderly patients taking opioids have also been found to have a greater risk for hospitalizations and increased vulnerability to adverse drug effects and interactions, such as respiratory depression. The 2016 CDC Guideline concludes that there must be "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients.[199]

440. According to a study published in the 2013 Journal of American Medicine, veterans returning from Iraq and Afghanistan who were prescribed opioids have a higher incidence of adverse clinical outcomes, such as overdoses and self-inflicted and accidental injuries. A 2008 survey showed that prescription drug misuse among military personnel doubled from 2002 to 2005, and then nearly tripled again over the next three years. Veterans are twice as likely as non-veterans to die from an opioid overdose.

441. Yet the Marketing Defendants deliberately targeted veterans with deceptive

[198] 2016 CDC Guideline, *supra* n. 139.
[199] *Id*. at 27.

marketing. For example, a 2009 publication sponsored by Purdue, Endo, and Janssen, and distributed by APF with grants from Janssen and Endo, was written as a personal narrative of one veteran but was in fact another vehicle for opioid promotion. Called *Exit Wounds*, the publication describes opioids as "underused" and the "gold standard of pain medications" while failing to disclose significant risks of opioid use, including the risks of fatal interactions with benzodiazepines. According to a VA Office of Inspector General Report, 92.6% of veterans who were prescribed opioid drugs were also prescribed benzodiazepines, despite the increased danger of respiratory depression from combining the two drugs.

442. Opioid prescriptions have dramatically increased for veterans and the elderly. Since 2007, prescriptions for the elderly have grown at twice the rate of prescriptions for adults between the ages of 40 and 59. And in 2009, military doctors wrote 3.8 million prescriptions for narcotic pain pills—four times as many as they did in 2001.

H. The Marketing Defendants' Scheme Succeeded, Creating a Public Health Epidemic

1. The Marketing Defendants Dramatically Expanded Opioid Prescribing and Use

443. The Marketing Defendants necessarily expected a return on the enormous investment they made in their deceptive marketing scheme, and they worked to measure and expand their success. Their own documents show that they knew they were influencing prescribers and increasing prescriptions. Studies also show that in doing so, they fueled an epidemic of addiction and abuse.

444. Cephalon also recognized the return of its efforts to market Actiq and Fentora off-label for chronic pain. In 2000, Actiq generated $15 million in sales. By 2002, Actiq sales had increased by 92%, which Cephalon attributed to "a dedicated sales force for ACTIQ" and "ongoing changes to [its] marketing approach including hiring additional sales representatives and targeting

our marketing efforts to pain specialists."[200] Actiq became Cephalon's second best-selling drug. By the end of 2006, Actiq's sales had exceeded $500 million.[201] Only 1% of the 187,076 prescriptions for Actiq filled at retail pharmacies during the first six months of 2006 were prescribed by oncologists. One measure suggested that "more than 80 percent of patients who use[d] the drug don't have cancer."[202]

445. Each of the Marketing Defendants tracked the impact of their marketing efforts to measure their impact in changing doctors' perceptions and prescribing of their drugs. They purchased prescribing and survey data that allowed them to closely monitor these trends, and they did actively monitor them. For instance, they monitored doctors' prescribing before and after detailing visits and before and after speaker programs. Defendants continued and, in many cases, expanded and refined their aggressive and deceptive marketing for one reason: it worked. As described in this Complaint, both in specific instances (e.g., the low abuse potential of various Defendants' opioids), and more generally, Defendants' marketing changed prescribers' willingness to prescribe opioids, led them to prescribe more of their opioids, and persuaded them not to stop prescribing opioids or to switch to "safer" opioids, such as ADF.

446. This success would have come as no surprise. Drug company marketing materially impacts doctors' prescribing behavior.[203] The effects of sales calls on prescribers' behavior is well

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[200] Cephalon, Inc. Annual Report (Form 10-K) at 28 (Mar. 31, 2003), https://www.sec.gov/Archives/edgar/data/873364/000104746903011137/a2105971z10-k.htm.
[201] Carreyrou, *Narcotic Lollipop*.
[202] *Id.*

[203] *See, e.g.*, P. Manchanda & P. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 (2-3) Mktg. Letters 129 (2004) (detailing has a positive impact on prescriptions written); I. Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33(6) Health Affairs 1014 (2014) (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in on-label

documented in the literature. One study examined four practices, including visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives have the strongest effect on drug utilization. An additional study found that doctor meetings with sales representatives are related to changes in both prescribing practices and requests by physicians to add the drugs to hospitals' formularies.

447. Marketing Defendants spent millions of dollars to market their drugs to prescribers and patients and meticulously tracked their return on that investment. In one recent survey published by the AMA, even though nine in ten general practitioners reported prescription drug abuse to be a moderate to large problem in their communities, 88% of the respondents said they were confident in their prescribing skills, and nearly half were comfortable using opioids for chronic non-cancer pain.[204] These results are directly due to the Marketing Defendants' fraudulent marketing campaign focused on several misrepresentations.

448. Thus, both independent studies and Defendants' own tracking confirm that Defendants' marketing scheme dramatically increased their sales.

2. The Marketing Defendants' Deception In Expanding Their Market Created And Fueled The Opioid Epidemic.

449. Independent research demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."[205] It has been

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use of promoted drugs); *see also* A. Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J. Pub. Health 221 (2009) (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997 to 6.2 million in 2002 to a doubling of Purdue's sales force and trebling of annual sales calls).

[204] CS Hwang et al., *Prescription Drug Abuse: A National Survey of Primary Care Physicians*, 175 JAMA Intern. Med. 302 (2014), doi: 10.1001/jamainternmed.2014.6520, https://www.ncbi.nlm.nih.gov/pubmed/25485657.

[205] Theodore J. Cicero et al., *Relationship Between Therapeutic Use and Abuse of Opioid Analgesics in Rural, Suburban, and Urban Locations in the United States*, 16

estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions.

450. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes." The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[206]

451. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

I. Each of the Marketing Defendants Made Materially Deceptive Statements and Concealed Material Facts

452. As alleged herein, the Marketing Defendants made and/or disseminated deceptive statements regarding material facts and further concealed material facts in the course of manufacturing, marketing, and selling prescription opioids. The Marketing Defendants' actions were intentional and/or unlawful. Such statements include, but are not limited to, those set out below and alleged throughout this Complaint**.**

453. As a part of their deceptive marketing scheme, the Marketing Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the United States. For example, the Marketing Defendants focused their deceptive marketing on primary care doctors,

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Pharmacoepidemiology and Drug Safety, 827-40 (2007), doi: 10.1002/pds.1452, https://www.cdhs.udel.edu/content-sub-site/Documents/Publications/Relationship%20Between%20Therapeutic%20Use%20and%20Abuse%20of%20Opioid%20Analgesics.pdf.

[206] *See* Califf, et al., *supra* n. 8.

who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept the Marketing Defendants' misrepresentations.

1. Purdue

454. Defendant Purdue made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;

b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

c. Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;

d. Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;

e. Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

g. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

h. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

i. Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

l. Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including

known rates of abuse and addiction and the lack of validation for long-term efficacy;

n. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

o. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

p. Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;

q. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing; and

r. Withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioid, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers.

455. More specifically, Defendant Purdue made and/or disseminated deceptive statements, and promoted a culture that mislead doctors and patients into believing opioids were safe for chronic care, including, but not limited to, the following:

a. In 1998, Purdue distributed 15,000 copies of an OxyContin video to physicians without submitting it to the FDA for review, an oversight later acknowledged by Purdue. In 2001, Purdue submitted to the FDA a second version of the video,

which the FDA did not review until October 2002—after the General Accounting Office inquired about its content. After its review, the FDA concluded that the video minimized the risks from OxyContin and made unsubstantiated claims regarding its benefits to patients.[207]

b. According to training materials, Purdue instructed sales representatives to assure doctors—repeatedly and without evidence—that "fewer than one per cent" of patients who took OxyContin became addicted. (In 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was thirteen per cent.)[208]

c. Andrew Kolodny, the co-director of the Opioid Policy Research Collaborative, at Brandeis University, has worked with hundreds of patients addicted to opioids. He has stated that, though many fatal overdoses have resulted from opioids other than OxyContin, the crisis was initially precipitated by a shift in the culture of prescribing—a shift carefully engineered by Purdue. "If you look at the prescribing trends for all the different opioids, it's in 1996 that prescribing really takes off," Kolodny said. "It's not a coincidence. That was the year Purdue launched a multifaceted campaign that misinformed the medical community about the risks."[209]

d. "Purdue had a speakers' bureau, and it paid several thousand clinicians to attend medical conferences and deliver presentations about the merits of the drug.

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[207] Patrick R. Keefe, *The Family that Built an Empire of Pain*, THE NEW YORKER (Oct. 30, 2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain.
[208] *Id.*
[209] *Id.*

Doctors were offered all-expenses-paid trips to pain-management seminars in places like Boca Raton. Such spending was worth the investment: doctors who attended these seminars in 1996 wrote OxyContin prescriptions more than twice as often as those who didn't. The company advertised in medical journals, sponsored Web sites about chronic pain, and distributed a dizzying variety of OxyContin swag: fishing hats, plush toys, luggage tags. Purdue also produced promotional videos featuring satisfied patients—like a construction worker who talked about how OxyContin had eased his chronic back pain, allowing him to return to work. The videos, which also included testimonials from pain specialists, were sent to tens of thousands of doctors. The marketing of OxyContin relied on an empirical circularity: the company convinced doctors of the drug's safety with literature that had been produced by doctors who were paid, or funded, by the company."[210]

e. Purdue encouraged sales representatives to increase sales of OxyContin through a lucrative bonus system, which resulted in a large number of visits to physicians with high rates of opioid prescriptions. In 2001, Purdue paid $40 million in bonuses to its sales representatives.[211]

f. Purdue claimed that the risk of addiction from OxyContin was extremely small and trained its sales representatives to carry the message that the risk of addiction was "less than one percent," while knowing that there was no empirical support for that statement.

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[210] *Id.*

[211] *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/.

g. By 2003, the Drug Enforcement Administration had found that Purdue's "aggressive methods" had "very much exacerbated OxyContin's widespread abuse." Rogelio Guevara, a senior official at the D.E.A., concluded that Purdue had "deliberately minimized" the risks associated with the drug.[212]

456. "From 1996 to 2001, Purdue conducted more than 40 national pain-management and speaker training conferences at resorts in Florida, Arizona, and California. More than 5000 physicians, pharmacists, and nurses attended these all-expenses-paid symposia, where they were recruited and trained for Purdue's national speaker bureau. It is well documented that this type of pharmaceutical company symposium influences physicians' prescribing even though the physicians who attend such symposia believe that such enticements do not alter their prescribing patterns."[213]

457. As noted above, Purdue utilized Front Groups to help disseminate and defend its false messages. Between January 2012 and March 2017, Purdue made the following contributions:

Academy of Integrative Pain Management	$1,091,024.86
American Academy of Pain Management	$725,584.95
ACS Cancer Action Network	$168,500.00[214]
American Chronic Pain Association	$312,470.00

[212] *The Family that Built an Empire of Pain*, https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain

[213] Art Van Zee, MD, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 Am. Journal of Public Health 2 (February 2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/.

[214] Payments from Purdue to the American Cancer Society Cancer Action Network include payments to the American Cancer Society that could potentially have applied to the Cancer Action Network. Production from Purdue Pharma to the Senate Homeland Security and Governmental Affairs Committee (Nov. 13, 2017).

American Geriatrics Society	$11,785.00[215]
American Pain Foundation	$25,000
American Pain Society	$542,259.52
American Society of Pain Educators	$30,000
American Society of Pain Management Nursing	$242,535.00
The Center for Practical Bioethics	$145,095.00
U.S. Pain Foundation	$359,300.00
Washington Legal Foundation	$500,000.00
TOTAL	**$4,153,554.33**

2. Endo

458. Defendant Endo made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

[215] The AGS reported that Purdue also provided $40,000 in "corporate roundtable dues" to its AGS Health in Aging Foundation, a 501(c)(3) organization affiliated with the group, between 2012 and 2015. Letter from Nancy E. Lundebjerg, Chief Executive Office, American Geriatrics Society, to Sen. Claire McCaskill (Oct. 11, 2017).

c. Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;

d. Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;

e. Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;

f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

g. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

h. Providing needed financial support to pro-opioid pain organizations – including over $5 million to the organization responsible for many of the most egregious misrepresentations – that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

i. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

l. Directly distributing and assisting in the dissemination of literature written by pro- opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and

n. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

3. Janssen

459. Defendant Janssen made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

c. Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Janssen exercised final editorial control and approval;

d. Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;

e. Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;

f. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

g. Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

h. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

i. Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

l. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

m. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and

n. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

4. Depomed

460. Defendant Depomed has, since at least October 2011, made and/or disseminated untrue, false and deceptive statements, and concealed material facts in such a way to make their statements deceptive with respect to Lazanda and (with the acquisition from Janssen in January 2015) of Nucynta and Nucynta ER, including, but not limited to:

1. Promoting the usage of Lazanda with patients not suffering from cancer;
2. Endorsing, supporting, and pressuring its sales representative to target pain management physicians, particularly those who historically wrote large numbers of Lazanda-like drugs;
3. Discouragement of sales representatives from targeting physicians treating cancer patients in contradiction to the FDA approved warning indicating that Lazanda is only indicated "for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain;"
4. Training of sales representatives on how to deal with pushback from physicians;
5. Promotion of Nucynta and Nucynta ER for all manner of pain management while downplaying the drug's addictive nature;
6. Promoting its drugs as a safer alternative than other opioids;
7. Telling investors that Depomed is safe. August Moretti, Depomed's Senior Vice President and Chief Financial Officer, stated that "[a]lthough not in the label, there's a very low abuse profile and side effect rate."

5. Cephalon

461. Defendant Cephalon made and/or disseminated untrue, false and deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

c. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;

d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon's potent rapid-onset opioids;

e. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

f. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

g. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;

h. Directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;

i. Making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and

j. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events.

6. Actavis

462. Defendant Actavis made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;

b. Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;

c. Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and

d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

463. A Kadian prescriber guide deceptively represents that Kadian is more difficult to

abuse and less addictive than other opioids. Kadian's prescriber guide is full of disclaimers that Actavis has not done any studies on the topic and that the guide is "only intended to assist you in forming your own conclusion." However, the guide includes the following statements: 1) "unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users," and 2) "KADIAN may be less likely to be abused by health care providers and illicit users" because of "Slow onset of action," "Lower peak plasma morphine levels than equivalent doses of other formulations of morphine," "Long duration of action," and "Minimal fluctuations in peak to trough plasma levels of morphine at steady state." The guide is copyrighted by Actavis in 2007, before Actavis officially purchased Kadian from Alpharma.

7. Mallinckrodt

464. Defendant Mallinckrodt made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

8. Creating and promoting publications that misrepresented and trivialized the risks of addiction;
9. Creating and promoting publications that overstated the benefits of opioids for chronic pain; and
10. Making deceptive statements about pseudoaddiction.

J. Marketing Defendants' Prior Bad Acts

465. Defendants have long known about the dangers of their opioid products, and the alarming quantities in which they were pouring into communities all across the country, because they have been sued, fined, and criminally convicted for failing to mitigate these problems.

466. For example, in 2007 Purdue settled criminal and civil charges against it for

"misbranding" OxyContin. Purdue was forced to admit it illegally marketed and promoted OxyContin by claiming it was less addictive and less subject to abuse than other pain medications. Purdue agreed to pay nearly $635 million in fines, and three of its executives pled guilty to federal criminal charges for misleading regulators, doctors, and patients about OxyContin's risk of addiction and its potential to be abused. At the time, this was one of the largest settlements with a drug company for marketing misconduct.[216]

467. In 2015, the Indiana Department of Public Health determined that an HIV outbreak in Southeastern Indiana was linked to injection of the prescription painkiller Opana,[217] the first documented HIV outbreak in the United States associated with injection of a prescription painkiller. After the outbreak, the FDA required "that Endo Pharmaceuticals remove [Opana ER] from the market." The agency sought removal "based on its concern that the benefits of the drug may no longer outweigh its risks."[218]

468. In 2017, The Department of Justice fined Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.

K. The Distributor Defendants' Unlawful Distribution of Opioids

469. The Distributor Defendants owe a duty under, *inter alia*, Kentucky common law and statutory law to monitor, detect, investigate, refuse to fill, and report suspicious orders of

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[216] Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, N.Y. TIMES (May 10, 2007), http://www.nytimes.com/2007/05/10/business/11drug-web.html.

[217] Press Release, State of Ind. Health Dep't, HIV Outbreak in Southeastern Indiana, (Feb. 25, 2015), http://www.in.gov/activecalendar/EventList.aspx?fromdate=1/1/2015&todate=12/31/2015&display=Month&type=public&eventidn=210259&view=EventDetails&information_id=211489.

[218] Jen Christensen, *FDA wants Opioid Painkiller Pulled off Market,* CNN (June 8, 2017), https://www.cnn.com/2017/06/08/health/fda-opioid-opana-er-bn/index.html; Press Release, U.S. Food & Drug Admin., FDA Requests Removal of Opana ER for Risks Related to Abuse (June 8, 2017), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm.

prescription opioids as well as those orders which the Distributor Defendants knew or should have known were likely to be diverted.

470. The foreseeable harm from a breach of these duties was the medical, social, and financial consequences rippling through society, arising from the abuse of diverted opioids for nonmedical purposes.

471. Each Distributor Defendant repeatedly and purposefully breached its duties under Kentucky law. Such breaches are a direct and proximate causes of the widespread diversion of prescription opioids for nonmedical purposes, with the resultant medical and financial damages.

472. For over a decade, all the Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, Defendants are not permitted to engage in a limitless expansion of their sales through the unlawful sales of regulated painkillers. Rather, as described below, Defendants are subject to various duties to report the quantity of Schedule II controlled substances in order to monitor such substances and prevent oversupply and diversion into the illicit market.

473. The unlawful diversion of prescription opioids is a direct and proximate cause of the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality, with social and financial costs borne by, among others, individuals, families, health departments, and hospitals.

474. The Distributor Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid epidemic and causing the damages alleged herein.

L. Defendants Throughout the Supply Chain Deliberately Disregarded Their Duties to Maintain Effective Controls and to Identify, Report, and Take Steps to Halt Suspicious Orders

475. The Marketing Defendants created a vastly and dangerously larger market for

opioids. All of the Defendants compounded this harm by facilitating the supply of far more opioids that could have been justified to serve that market. The failure of the Defendants to maintain effective controls, and to investigate, report, and take steps to halt orders that they knew or should have known were suspicious breached both their statutory and common law duties.

476. Marketing Defendants' scheme was resoundingly successful. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—has become a commonplace, and often first-line, treatment. Marketing Defendants' deceptive marketing caused prescribing not only of their opioids, but also of opioids as a class, to skyrocket. According to the CDC opioid prescriptions, as measured by number of prescriptions and morphine milligram equivalent ("MME") per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S. While previously a small minority of opioid sales, today between 80% and 90% of opioids (measured by weight) used are for chronic pain. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids.

477. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses."[219] Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."[220]

[219] CDC, January 1, 2016 Morbidity and Mortality Weekly Report; Rudd, Rose A., et al., "Increases in drug and opioid overdose deaths—United States, 2000–2014." American Journal of Transplantation 16.4 (2016): 1323-1327.
[220] *Id.*

1. All Defendants Have a Duty to Guard Against, and Report, Unlawful Diversion and to Report and Prevent Suspicious Orders

478. Multiple sources impose duties on Defendants with respect to the supply of opioids, including the common law duty to exercise reasonable care. Each Defendant was required to register with the Commonwealth of Kentucky. KRS 315.005, *et. seq.*

479. Federal requirements impose a non-delegable duty upon registrants to design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

480. "Suspicious orders" include orders of an unusual size, orders of unusual frequency or orders deviating substantially from a normal pattern. See 21 C.F.R. § 1301.74(b). These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the customer base and the patterns throughout the relevant segment of the industry.

481. In addition to reporting all suspicious orders, the Distributor Defendants must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the recipient can determine that the

order is not likely to be diverted into illegal channels. *See Southwood Pharm., Inc*., 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F. 3d 206 (D.C. 2017). Regardless, all flagged orders must be reported. *Id*.

482. These prescription drugs are regulated for the purpose of providing a "closed" system intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.[221]

483. Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations define each participant's role and responsibilities."[222]

484. The FTC has recognized the unique role of distributors. Since their inception, Distributor Defendants have continued to integrate vertically by acquiring businesses that are related to the distribution of pharmaceutical products and health care supplies. In addition to the actual distribution of pharmaceuticals, as wholesalers, Distributor Defendants also offer their

[221] *See* 1970 U.S.C.C.A.N. 4566, 4571-72.

[222] Brief for Healthcare Distribution Mgmt. Association and National Ass'n of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. U.S. Drug Enf't Admin.* (No. 15-1335) (D.C. Cir. Apr. 4, 2016), 2016 WL 1321983, at *22 (hereinafter "Brief for HDMA and NACDS"). The Healthcare Distribution Mgmt. Ass'n (HDMA or HMA)—now known as the Healthcare Distribution Alliance (HDA) —is a national, not-for-profit trade association that represents the nation's primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation and Cardinal Health, Inc. *See generally* HDA, *About*, https://www.healthcaredistribution.org/about (last accessed Aug. 1, 2018). The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart. *See generally* NACDS, *Mission*, https://www.nacds.org/%20about/mission/ (last accessed Aug. 1, 2018).

pharmacy, or dispensing, customers a broad range of added services. For example, Distributor Defendants offer their pharmacies sophisticated ordering systems and access to an inventory management system and distribution facility that allows customers to reduce inventory carrying costs. Distributor Defendants are also able to use the combined purchase volume of their customers to negotiate the cost of goods with manufacturers and offer services that include software assistance and other database management support. *See Fed. Trade Comm'n v. Cardinal Health, Inc*., 12 F. Supp. 2d 34, 41 (D.D.C. 1998) (granting the FTC's motion for preliminary injunction and holding that the potential benefits to customers did not outweigh the potential anti-competitive effect of a proposed merger between Cardinal, Inc. and Bergen Brunswig Corp.). As a result of their acquisition of a diverse assortment of related businesses within the pharmaceutical industry, as well as the assortment of additional services they offer, Distributor Defendants have a unique insight into the ordering patterns and activities of their dispensing customers.

485. As the DEA advised the Distributor Defendants in a letter dated September 27, 2006, wholesale distributors are "one of the key components of the distribution chain. If the closed system is to function properly … distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as … the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[223]

486. The Distributor Defendants have admitted that they are responsible for reporting

[223] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006) (hereinafter "Rannazzisi Letter") ("This letter is being sent to every commercial entity in the United States registered with the Drug Enf't Admin. (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces."), *filed in Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.

suspicious orders.[224]

487. The DEA's September 27, 2006 letter also warned the Distributor Defendants that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, in addition to reporting suspicious orders, has a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."[225] The letter also instructs that "distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes."[226] The DEA warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."

488. The DEA sent a second letter to each of the Distributor Defendants on December 27, 2007.[227] This letter reminds the Distributor Defendants of their statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[228] The letter further explains:

489. The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders <u>when discovered</u> by the registrant. Filing a monthly report of completed transactions (*e.g.*, "excessive purchase report" or "high unity purchases") does not meet the regulatory requirement to report suspicious orders.

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[224] *See* Brief for HDMA and NACDS, *supra* n. 246, 2016 WL 1321983, at *4 ("[R]egulations ... in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders).").
[225] Rannazzisi Letter, *supra* note 247, at 2.
[226] *Id.* at 1.
[227] *Id.* at 2.
[228] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8.

490. The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive.

491. Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.[229]

492. Finally, the DEA letter references the Revocation of Registration issued in Southwood Pharmaceuticals, Inc., 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."[230]

493. The Distributor Defendants admit that they "have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."[231]

494. The Distributor Defendants knew they were required to monitor, detect, and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution Management Association (now known as the HDA, a front group of the Defendants, discussed below), the trade association of pharmaceutical distributors, explain that distributors are "[a]t the

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[229] *Id.*
[230] *Id.*
[231] *See* Amicus Curiae Brief of Healthcare Distribution Mgmt. Ass'n in Support of App. Cardinal Health, Inc., *Cardinal Health, Inc. v. U.S. Dep't of Justice*, No. 12- 5061 (D.C. Cir. May 9, 2012), 2012 WL 1637016, at *10 (hereinafter "Brief of HDMA in Support of Cardinal").

center of a sophisticated supply chain" and therefore "are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers." The guidelines set forth recommended steps in the "due diligence" process, and note in particular: If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.[232]

495. The DEA also repeatedly reminded the Defendants of their obligations to report and decline to fill suspicious orders. Responding to the proliferation of pharmacies operating on the internet that arranged illicit sales of enormous volumes of opioids to drug dealers and customers, the DEA began a major push to remind distributors of their obligations to prevent these kinds of abuses and educate them on how to meet these obligations. Since 2007, the DEA has hosted at least five conferences that provided registrants with updated information about diversion trends and regulatory changes. Each of the Distributor Defendants attended at least one of these conferences. The DEA has also briefed wholesalers regarding legal, regulatory, and due diligence responsibilities since 2006. During these briefings, the DEA pointed out the red flags wholesale distributors should look for to identify potential diversion.

496. Each of the Distributor Defendants sold prescription opioids, including hydrocodone and/or oxycodone, to retailers from which the Distributor Defendants knew prescription opioids were likely to be diverted.

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[232] Healthcare Distribution Mgmt. Ass'n (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances*, *filed in Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B).

497. Each Distributor Defendant owes a duty to monitor and detect suspicious orders of prescription opioids.

498. Each Distributor Defendant owes a duty under Kentucky law to investigate and refuse suspicious orders of prescription opioids.

499. Each Distributor Defendant owes a duty under Kentucky law to report suspicious orders of prescription opioids.

500. Each Distributor Defendant owes a duty under Kentucky law to prevent the diversion of prescription opioids into illicit markets throughout the United States.

501. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes and subsequent plague of opioid addiction, with costs and damages necessarily inflicted on and incurred by Plaintiff and others.

502. The foreseeable harm resulting from the diversion of prescription opioids for nonmedical purposes is abuse, addiction, morbidity and mortality, along with the costs imposed upon Plaintiff and others associated with the treatment of these conditions and related health consequences caused by opioid abuse.

503. Finding it impossible to legally achieve their ever-increasing sales ambitions, Defendants engaged in the common purpose of increasing the supply of opioids and fraudulently increasing the quotas that governed the manufacture and distribution of their prescription opioids.

504. Wholesale distributors such as the Distributor Defendants had close financial relationships with both Marketing Defendants and customers, for whom they provide a broad range of value added services that render them uniquely positioned to obtain information and control against diversion. These services often otherwise would not be provided by manufacturers to their dispensing customers and would be difficult and costly for the dispenser to reproduce. For

example, "[w]holesalers have sophisticated ordering systems that allow customers to electronically order and confirm their purchases, as well as to confirm the availability and prices of wholesalers' stock." *Fed. Trade Comm'n v. Cardinal Health, Inc*., 12 Supp. 2d 34, 41 (D.D.C. 1998). Through their generic source programs, wholesalers are also able "to combine the purchase volumes of customers and negotiate the cost of goods with manufacturers." Wholesalers typically also offer marketing programs, patient services, and other software to assist their dispensing customers.

505. Distributor Defendants had financial incentives from the Marketing Defendants to distribute higher volumes and thus to refrain from reporting or declining to fill suspicious orders. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit. Either way, the increased sales volumes result in increased profits.

506. The Marketing Defendants engaged in the practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids as a way to help them boost sales and better target their marketing efforts. The Washington Post has described the practice as industry-wide, and the Healthcare Distribution Alliance ("HDA") includes a "Contracts and Chargebacks Working Group," suggesting a standard practice. Further, in a recent settlement with the DEA, Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors)." The transaction information contains data relating to the direct customer sales of

controlled substances to "downstream registrants", meaning pharmacies or other dispensaries, such as hospitals. Marketing Defendants buy data from pharmacies as well. This exchange of information, upon information and belief, would have opened channels providing for the exchange of information revealing suspicious orders as well.

507. A dramatic example of the use of prescription information provided by IMS Health was described in Congressional testimony:

> **Mr. Greenwood:** Well, why do you want that [IMS Health] information then?
>
> **Mr. Friedman:** Well, we use that information to understand what is happening in terms of the development of use of our product in any area.
>
> Mr. Greenwood. And so the use of it--and I assume that part of it--a large part of it you want is to see how successful your marketing techniques are so that you can expend money in a particular region or among a particular group of physicians-- you look to see if your marketing practices are increased in sales. And, if not, you go back to the drawing board with your marketers and say, how come we spent "X" number of dollars, according to these physicians, and sales haven't responded. You do that kind of thing. Right?
>
> **Mr. Friedman:** Sure.[233]

[233] *Oxycontin: Its Use and Abuse*: *Hearing Before the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce House of Representatives*, 107th Cong. 54 (2001) (statements of James C. Greenwood, Member, Committee on Energy and Commerce and Michael Friedman, Executive Vice President and COO of Purdue Pharma, L.P.), *available at* https://www.gpo.gov/fdsys/pkg/CHRG-107hhrg75754/html/CHRG-107hhrg75754.htm.

508. The contractual relationships among the Defendants also include vault security programs. Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opiates. The Defendants negotiated agreements whereby the Marketing Defendants installed security vaults for the Distributor Defendants in exchange for agreements to maintain minimum sales performance thresholds. These agreements were used by the Defendants as a tool to violate their reporting and diversion duties in order to reach the required sales requirements. In addition, Defendants worked together to achieve their common purpose through trade or other organizations, such as the Pain Care Forum ("PCF") and the HDA.

2. Pain Care Forum

509. Pain Care Forum ("PCF") has been described as a coalition of drug makers, trade groups, and dozens of non-profit organizations supported by industry funding, including the Front Groups described in this Complaint. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

510. The Center for Public Integrity and The Associated Press obtained "internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse."[234] Specifically, PCF members spent over $740 million lobbying in the nation's capital and in all 50 statehouses on an array of issues, including opioid-related measures.[235]

[234] Matthew Perrone, *Pro-Painkiller echo chamber shaped policy amid drug epidemic*, The Center for Public Integrity (Sept. 19, 2017, 12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic (emphasis added).
[235] *Id*.

511. The Defendants who stood to profit from expanded prescription opioid use are members of and/or participants in the PCF.[236] In 2012, membership and participating organizations included Endo, Purdue, Actavis and Cephalon. Each of the Marketing Defendants worked together through the PCF. But, the Marketing Defendants were not alone. The Distributor Defendants actively participated, and continue to participate, in the PCF through, at a minimum, their trade organization, the Healthcare Distribution Alliance (the "HDA").[237] The Distributor Defendants participated directly in the PCF as well.

3. The HDA

512. Additionally, the HDA led to the formation of interpersonal relationships and an organization among the Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Marketing Defendants, including Actavis, Endo, Purdue, Mallinckrodt and Cephalon, were members of the HDA.[238] Additionally, the HDA and each of the Distributor Defendants, eagerly sought the active membership and participation of the Marketing Defendants by advocating for the many benefits of members, including "strengthening . . . alliances."[239]

513. Beyond strengthening alliances, the benefits of HDA membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's

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[236] *PAIN CARE FORUM 2012 Meetings Schedule*, (last updated Dec. 2011), https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf.

[237] *Id*. The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc. and the Group President, Pharmaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation. *Executive Committee*, Healthcare Distribution Alliance (last accessed on Aug. 1, 2018), https://www.healthcaredistribution.org/about/executive-committee%20.

[238] *Manufacturer Membership*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/about/membership/manufacturer (last accessed Aug. 1, 2018).

[239] *Id*.

members-only Business and Leadership Conference," "networking with HDA wholesale distributor members," "opportunities to host and sponsor HDA Board of Directors events," "participate on HDA committees, task forces and working groups with peers and trading partners," and "make connections."[240] The HDA and the Distributor Defendants used membership in the HDA as an opportunity to create interpersonal and ongoing organizational relationships and "alliances" between the Marketing and Distributor Defendants.

514. The application for manufacturer membership in the HDA further indicates the level of connection among the Defendants and the level of insight that they had into each other's businesses.[241] For example, the manufacturer membership application must be signed by a "senior company executive," and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company.

515. The HDA application also requests that the manufacturer identify its current distribution information, including the facility name and contact information. Manufacturer members were also asked to identify their "most recent year end net sales" through wholesale distributors, including the Distributor Defendants AmerisourceBergen, Anda, Cardinal, and Henry Schein and their subsidiaries.

516. The closed meetings of the HDA's councils, committees, task forces and working groups provided the Marketing and Distributor Defendants with the opportunity to work closely together, confidentially, to develop and further the common purpose and interests of the enterprise.

517. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences to

[240] *Id.*
[241] *Id.*

the Marketing Defendants as an opportunity to "bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues."[242] The conferences also gave the Marketing and Distributor Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry."[243] The HDA and its conferences were significant opportunities for the Marketing and Distributor Defendants to interact at a high-level of leadership. The Marketing Defendants embraced this opportunity by attending and sponsoring these events.[244]

518. After becoming members of the HDA, Defendants were eligible to participate on councils, committees, task forces and working groups, including:

a. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues."

b. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce." Participation in this committee includes distributor and manufacturer members.

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[242] *Business and Leadership Conference – Information for Manufacturers*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/events/2015-business-and- leadership-conference/blc-for-manufacturers (last accessed Aug. 1, 2018, and no longer available).

[243] *Id.*

[244] *2015 Distribution Management Conference and Expo*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/events/2015-distribution-management-conference. (last accessed Aug. 1, 2018).

c. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement." Participation in this committee includes distributor and manufacturer members.

d. Manufacturer Government Affairs Advisory Committee: "This committee provides a forum for briefing HDA's manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement." Participation in this committee includes manufacturer members.

e. Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals." Participation in this group includes manufacturer and distributor members.

519. The Distributor Defendants and Marketing Defendants also participated, through the HDA, in Webinars and other meetings designed to exchange detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and

invoices.[245] For example, on April 27, 2011, the HDA offered a Webinar to "accurately and effectively exchange business transactions between distributors and manufacturers…" The Marketing Defendants used this information to gather high-level data regarding overall distribution and to direct the Distributor Defendants on how to most effectively sell prescription opioids.

520. Taken together, the interaction and length of the relationships between and among the Marketing and Distributor Defendants reflect a deep level of interaction and cooperation between two groups in a tightly knit industry. The Marketing and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

521. The HDA and the Pain Care Forum are but two examples of the overlapping relationships and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the Defendants were in communication and cooperation.

522. Publications and guidelines issued by the HDA confirm that the Defendants utilized their membership in the HDA to form agreements. Specifically, in the fall of 2008, the HDA published the *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances* (the "Industry Compliance Guidelines") regarding diversion. As the HDA explained in an amicus brief, the Industry Compliance Guidelines were the result of "[a] committee of HDMA members contribut[ing] to the development of this publication" beginning in late 2007.

523. This statement by the HDA and the Industry Compliance Guidelines support the

[245] *Webinars*, Healthcare Distribution Alliance, (last accessed on Sept. 14, 2017), https://www.healthcaredistribution.org/resources/webinar-leveraging-edi.

allegation that Defendants utilized the HDA to form agreements about their approach to their duties under the CSA. As John M. Gray, President/CEO of the HDA stated to the Energy and Commerce Subcommittee on Health in April 2014, it is "difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications." Here, it is apparent that all of the Defendants found the same balance – an overwhelming pattern and practice of failing to identify, report or halt suspicious orders, and failure to prevent diversion.

524. The Defendants' scheme had a decision-making structure driven by the Marketing Defendants and corroborated by the Distributor Defendants. The Marketing Defendants worked together to control the state and federal government's response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion and identify suspicious orders and report them to the DEA.

525. The Defendants worked together to control the flow of information and to influence state and federal governments to pass legislation that supported the use of opioids and limited the authority of law enforcement to rein in illicit or inappropriate prescribing and distribution. The Marketing and Distributor Defendants did this through their participation in the PCF and HDA.

526. The Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas, and Procurement Quotas allowed by the DEA remained artificially high. In so doing, they ensured that suspicious orders were not reported to the DEA, and, further, in so doing, they ensured that the DEA had no basis for either refusing to increase production quotas or decreasing production quotas due to diversion.

527. The Defendants also had reciprocal obligations under the CSA to report suspicious orders of other parties if they became aware of them. Defendants were thus collectively responsible

for each other's compliance with reporting obligations.

528. Defendants thus knew that their own conduct could be reported by other distributors or manufacturers and that their failure to report suspicious orders they filled could be brought to the DEA's attention. As a result, Defendants had an incentive to communicate with each other about the reporting of suspicious orders to ensure consistency in their dealings with DEA.

529. The desired consistency was achieved. As described below, none of the Defendants reported suspicious orders and the flow of opioids continued unimpeded.

4. Defendants Were Aware of and Have Acknowledged Their Obligations to Prevent Diversion and to Report and Take Steps to Halt Suspicious Orders

530. The reason for the reporting rules is to create a "closed" system intended to control the supply and reduce the diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control. Both because distributors handle such large volumes of controlled substances, and because they are uniquely positioned, based on their knowledge of their customers and orders, as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, distributors' obligation to maintain effective controls to prevent diversion of controlled substances is critical. Should a distributor deviate from these checks and balances, the closed system of distribution, designed to prevent diversion, collapses.[246]

531. Defendants were well aware they had an important role to play in this system, and also knew or should have known that their failure to comply with their obligations would have serious consequences.

[246] *See* Rannazzisi Decl. ¶ 10, filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-2.

5. Defendants Kept Careful Track of Prescribing Data and Knew About Suspicious Orders and Prescribers

532. The data that reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's Confidential Automation of Reports and Consolidated Orders System (ARCOS) database. The data necessary to identify with specificity the transactions that were suspicious is in possession of the Distributor and Marketing Defendants but has not been disclosed to the public.

533. Publicly available information confirms that Distributor and Marketing Defendants funneled far more opioids into Kentucky (and into communities across the United States) than could have been expected to serve legitimate medical use and ignored other red flags of suspicious orders. This information, along with the information known only to Distributor and Marketing Defendants, would have alerted them to potentially suspicious orders of opioids.

534. This information includes the following facts:

a. distributors and manufacturers have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy and includes the volume of opioids, dose, and the distribution of other controlled and non-controlled substances;

b. manufacturers make use of that data to target their marketing and, for that purpose, regularly monitor the activity of doctors and pharmacies;

c. manufacturers and distributors regularly visit pharmacies and doctors to promote and provide their products and services, which allows them to observe red flags of diversion;

d. Distributor Defendants together account for approximately 90% of all revenues from prescription drug distribution in the United States, and each

plays such a large part in the distribution of opioids that its own volume provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic area; and

e. Marketing Defendants purchased chargeback data (in return for discounts to Distributor Defendants) that allowed them to monitor the combined flow of opioids into a pharmacy or geographic area.

535. The conclusion that Defendants were on notice of the problems of abuse and diversion follows inescapably from the fact that they flooded communities with opioids in quantities that they knew or should have known exceeded any legitimate market for opioids-even the wider market for chronic pain.

536. At all relevant times, the Defendants were in possession of national, regional, state, and local prescriber-and patient-level data that allowed them to track prescribing patterns over time. They obtained this information from data companies, including but not limited to: IMS Health, QuintilesIMS, IQVIA, Pharmaceutical Data Services, Source Healthcare Analytics, NDS Health Information Services, Verispan, Quintiles, SDI Health, ArcLight, Scriptline, Wolters Kluwer, and/or PRA Health Science, and all of their predecessors or successors in interest (the "Data Vendors").

537. The Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007, was intended to help the Defendants identify suspicious orders or customers who were likely to divert prescription opioids.[247] The "know your customer" questionnaires informed the Defendants of the

[247] *Suggested Questions a Distributor should ask prior to shipping controlled substances*, DEA, https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf; Richard Widup, Jr., Kathleen H. Dooley, Esq. *Pharmaceutical Product Diversion: Beyond the PDMA*,

number of pills that the pharmacies sold, how many non-controlled substances were sold compared to controlled substances, whether the pharmacy purchased opioids from other distributors, and the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, and others. These questionnaires put the recipients on notice of suspicious orders.

538. Defendants purchased nationwide, regional, state, and local prescriber- and patient-level data from the Data Vendors that allowed them to track prescribing trends, identify suspicious orders, identify patients who were doctor shopping, identify pill mills, etc. The Data Vendors' information purchased by the Defendants allowed them to view, analyze, compute, and track their competitors' sales, and to compare and analyze market share information.[248]

539. IMS Health, for example, provided Defendants with reports detailing prescriber behavior and the number of prescriptions written between competing products.[249]

540. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies that were created by Cardinal (ArcLight), provided the Defendants with charts analyzing the weekly prescribing patterns of multiple physicians, organized by territory, regarding competing drugs and analyzed the market share of those drugs.[250]

541. This information allowed the Defendants to track and identify instances of

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Purdue Pharma and McGuireWoods LLC, https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf.

[248] A Verispan representative testified that the Supply Chain Defendants use the prescribing information to "drive market share." *Sorrell v. IMS Health Inc.*, 2011 WL 661712, *9-10 (Feb. 22, 2011).

[249] Paul Kallukaran & Jerry Kagan, *Data Mining at IMS HEALTH: How we Turned a Mountain of Data into a Few Information-rich Molehills*, http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.198.349&rep=rep1&type=pdf, Figure 2 at p. 3 (last accessed Aug. 1, 2018).

[250] *Sorrell v. IMS Health Inc.*, 2011 WL 705207, at *467-471 (Feb. 22, 2011).

overprescribing. In fact, one of the Data Vendors' experts testified that the Data Vendors' information could be used to track, identify, report and halt suspicious orders of controlled substances.[251] Defendants were, therefore, collectively aware of the suspicious orders that flowed from their facilities.

542. Defendants refused to identify, investigate, and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings. As described in detail below, Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012[252] and 117 recommended decisions in registrant actions from The Office of Administrative Law Judges. These numbers include 76 actions involving orders to show cause and 41 actions involving immediate suspension orders, all for failure to report suspicious orders.[253]

543. Sales representatives were also aware that the prescription opioids they were promoting were being diverted, often with lethal consequences. As a sales representative wrote on a public forum:

544. Actions have consequences - so some patient gets Rx'd the 80mg OxyContin when they probably could have done okay on the 20mg (but their doctor got "sold" on the 80mg) and their teen son/daughter/child's teen friend finds the pill bottle and takes out a few 80's... next they're at a pill party with other teens and some kid picks out a green pill from the bowl... they go

[251] In *Sorrell*, expert Eugene "Mick" Kolassa testified, on behalf of the Data Vender, that "a firm that sells narcotic analgesics was able to use prescriber-identifiable information to identify physicians that seemed to be prescribing an inordinately high number of prescriptions for their product." *Id*; *see also* Joint Appendix in *Sorrell v. IMS Health*, 2011 WL 687134, at *204 (Feb. 22, 2011).
[252] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.
[253] *Id.*

to sleep and don't wake up (because they don't understand respiratory depression). Stupid decision for a teen to make...yes... but do they really deserve to die?

545. Moreover, Defendants' sales incentives rewarded sales representatives who happened to have pill mills within their territories, enticing those representatives to look the other way even when their in-person visits to such clinics should have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away to get prescriptions, the DEA's diversion unit raided the clinic, and prosecutors eventually filed criminal charges against the doctors. But Purdue's sales representative for that territory, Eric Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time, Wilson was Purdue's top-ranked sales representative.[254] In response to news stories about this clinic, Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication inappropriately, such activity would continue regardless of whether we contacted the doctor or not."[255]

546. In another example, a Purdue sales manager informed her supervisors in 2009 about a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her sales representative, "it was packed with a line out the door, with people who looked like gang members," and that she felt "very certain that this an organized drug ring[.]"[256] She wrote, "This is clearly diversion. Shouldn't the DEA be contacted about this?" But her supervisor at Purdue responded that while they were "considering all angles," it was "really up to [the wholesaler] to

[254] *Pain Killer*, *supra* n. 63, at 298-300.
[255] *Id*.
[256] Harriet Ryan et al., *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drug maker knew*, LOS ANGELES TIMES (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/.

make the report."[257] This pill mill was the source of 1.1 million pills trafficked to Everett, Washington, a city of around 100,000 people. Purdue waited until after the clinic was shut down in 2010 to inform the authorities.

547. Defendants' obligation to report suspicious prescribing ran head on into their marketing strategy. Defendants did identify doctors who were their most prolific prescribers. However, this was done not to report them, but to market to them. It would make little sense to focus on marketing to doctors who may be engaged in improper prescribing only to report them to law enforcement.

548. Defendants purchased data from IMS Health (now IQVIA) or other proprietary sources to identify doctors to target for marketing and to monitor their own and competitors' sales. Marketing visits were focused on increasing, sustaining, or converting the prescriptions of the biggest prescribers, particularly through aggressive, high frequency detailing visits.

549. This focus on marketing to the highest prescribers demonstrates that manufacturers were keenly aware of the doctors who were writing large quantities of opioids. But instead of investigating or reporting those doctors, Defendants were singularly focused on maintaining, capturing, or increasing their sales.

550. Whenever examples of opioid diversion and abuse have drawn media attention, Purdue and other Marketing Defendants have consistently blamed "bad actors." For example, in 2001, during a Congressional hearing, Purdue's attorney Howard Udell answered pointed questions about how it was that Purdue could utilize IMS Health data to assess their marketing efforts but not notice a particularly egregious pill mill in Pennsylvania run by a doctor named Richard Paolino. Udell asserted that Purdue was "fooled" by the doctor: "The picture that is painted

[257] *Id.*

in the newspaper [of Dr. Paolino] is of a horrible, bad actor, someone who preyed upon this community, who caused untold suffering. And he fooled us all. He fooled law enforcement. He fooled the DEA. He fooled local law enforcement. He fooled us."[258]

551. But given the closeness with which they monitored prescribing patterns through IMS Health data, the Defendants either knew or chose not to know of the obvious drug diversions. In fact, a local pharmacist had noticed the volume of prescriptions coming from Paolino's clinic and alerted authorities. Purdue had the prescribing data from the clinic and alerted no one. Indeed, a Purdue executive referred to Purdue's tracking system and database as a "gold mine" and acknowledged that Purdue could identify highly suspicious volumes of prescriptions.

552. As discussed below, Endo knew that Opana ER was being widely abused. Yet, the New York Attorney General revealed, based on information obtained in an investigation into Endo, that Endo sales representatives were not aware that they had a duty to report suspicious activity and were not trained on the company's policies or duties to report suspicious activity, and Endo paid bonuses to sales representatives for detailing prescribers who were subsequently arrested for illegal prescribing.

553. Sales representatives making in-person visits to such clinics were likewise not fooled. But as pill mills were lucrative for the manufacturers and individual sales representatives alike, Marketing Defendants and their employees turned a collective blind eye, allowing certain clinics to dispense staggering quantities of potent opioids and feigning surprise when the most egregious examples eventually made the nightly news.

[258] *Pain Killer*, *supra* n. 63, at 179.

6. Defendants Failed to Report Suspicious Orders or Otherwise Act to Prevent Diversion

554. As discussed above, Defendants failed to report suspicious orders, prevent diversion, or otherwise control the supply of opioids flowing into communities across America. Despite the notice described above, Defendants continued to pump massive quantities of opioids into communities in disregard of their legal duties to control the supply, prevent diversion, and report and take steps to halt suspicious orders.

555. Governmental agencies and regulators have confirmed (and in some cases Defendants have admitted) that Defendants did not meet their obligations and have uncovered especially blatant wrongdoing.

556. For example, in 2017, the Department of Justice fined Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements. The government alleged that "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances - orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."

557. On December 23, 2016, Cardinal agreed to pay the United States $44 million to resolve allegations that it violated the CSA in Maryland, Florida, and New York by failing to report suspicious orders of controlled substances, including oxycodone, to the DEA. In the settlement agreement, Cardinal admitted, accepted, and acknowledged that it had violated the CSA between January 1, 2009 and May 14, 2012 by failing to:

a. "timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. §1301.74(b)";

b. "maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 C.F.R. §1301.74, including the failure to make records and reports required by the CSA or DEA's regulations for which a penalty may be imposed under 21 U.S.C. §842(a)(5)"; and

c. "execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA 'Form 222' order forms and their electronic equivalent for Schedule II controlled substances, as required by 21 U.S.C. §828 and 21 C.F.R. Part 1305."

558. In 2012, the State of West Virginia sued AmerisourceBergen and Cardinal, as well as several smaller wholesalers, for numerous causes of action, including violations of the CSA, consumer credit and protection and antitrust laws, and the creation of a public nuisance. Unsealed court records from that case demonstrate that AmerisourceBergen, along with Cardinal, shipped 423 million pain pills to West Virginia between 2007 and 2012. AmerisourceBergen itself shipped 80.3 million hydrocodone pills and 38.4 million oxycodone pills during that time period. These quantities demonstrate that the Defendants failed to control the supply chain or to report and take steps to halt suspicious orders. In 2016, AmerisourceBergen agreed to settle the West Virginia lawsuit for $16 million to the state; Cardinal settled for $20 million.

559. Henry Schein, too, is a repeat offender. Since the company's inception, it has been subjected to repeated disciplinary actions across the United States for its sale and/or distribution of dangerous drugs to persons or facilities not licensed or otherwise authorized to possess such drugs.

560. In 2014, Henry Schein Animal Health was investigated by the State of Ohio Board of Pharmacy due to its sale/distribution of wholesale dangerous drugs to an entity not holding a valid Ohio license. It reached a settlement with the Ohio Board of Pharmacy related to this investigation in 2015.

561. Records from a disciplinary proceeding against a Wisconsin-licensed medical practitioner reveal that from May 2005 through September 2006, Henry Schein continued to deliver opioids to the provider, despite the fact that his license had been suspended for inappropriate prescribing of opioids.

562. Thus, Defendants have admitted to disregarding their duties. They have admitted that they pumped massive quantities of opioids into communities around the country despite their obligations to control the supply, prevent diversions, and report and take steps to halt suspicious orders.

7. Defendants Delayed a Response to the Opioid Crisis by Pretending to Cooperate with Law Enforcement

563. When a manufacturer or distributor does not report or stop suspicious orders, prescriptions for controlled substances may be written and dispensed to individuals who abuse them or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and results in opioid-related overdoses. Without reporting by those involved in the supply chain, law enforcement may be delayed in taking action - or may not know to take action at all.

564. After being caught failing to comply with particular obligations at particular facilities, Distributor Defendants made broad promises to change their ways and insisted that they sought to be good corporate citizens.

565. More generally, the Distributor Defendants publicly portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others to prevent

diversion of these dangerous drugs. For example, Defendant Cardinal claims that: "We challenge ourselves to best utilize our assets, expertise and influence to make our communities stronger and our world more sustainable, while governing our activities as a good corporate citizen in compliance with all regulatory requirements and with a belief that doing 'the right thing' serves everyone." Defendant Cardinal likewise claims to "lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse." Along the same lines, it claims to "maintain a sophisticated, state-of-the-art program to identify, block and report to regulators those orders of prescription-controlled medications that do not meet [its] strict criteria." Defendant Cardinal also promotes funding it provides for "Generation Rx," which funds grants related to prescription drug misuse. A Cardinal executive recently claimed that Cardinal uses "advanced analytics" to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

566. Along the same lines, Defendant AmerisourceBergen has taken the public position that it is "work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare delivery to help find solutions that will support appropriate access while limiting misuse of controlled substances." A company spokeswoman also provided assurance that: "At AmerisourceBergen, we are committed to the safe and efficient delivery of controlled substances to meet the medical needs of patients."

567. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Distributor Defendants, through their trade associations, HDMA and NACDS, filed an amicus brief in *Masters Pharmaceuticals*, which made the following statements:[259]

[259] Brief for HDMA and NACDS, *supra* n. 246, 2016 WL 1321983, at *3-4, *25.

a. "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."

b. "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process."

568. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, the Distributor Defendants not only acknowledged that they understood their obligations under the law, but they further asserted that their conduct was in compliance with those obligations.

569. Defendant Mallinckrodt similarly claims to be "committed . . . to fighting opioid misuse and abuse," and further asserts that: "In key areas, our initiatives go beyond what is required by law. We address diversion and abuse through a multidimensional approach that includes educational efforts, monitoring for suspicious orders of controlled substances . . ."

570. Other Marketing Defendants also misrepresented their compliance with their legal duties and their cooperation with law enforcement. Purdue serves as a hallmark example of such wrongful conduct. Purdue deceptively and unfairly failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its "constructive role in the fight against opioid abuse," including its commitment to ADF opioids and its "strong record of coordination with law enforcement.[260]

[260] Purdue, *Setting The Record Straight On OxyContin's FDA-Approved Label* (May 5, 2016), http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontins-fda-approved-label/; Purdue, *Setting The Record Straight On Our Anti-Diversion*

571. At the heart of Purdue's public outreach is the claim that it works hand-in-glove with law enforcement and government agencies to combat opioid abuse and diversion. Purdue has consistently trumpeted this partnership since at least 2008, and the message of close cooperation is in virtually all of Purdue's recent pronouncements in response to the opioid epidemic.

572. Touting the benefits of ADF opioids, Purdue's website asserts: "[W]e are acutely aware of the public health risks these powerful medications create . . . . That's why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid abuse and misuse . . . ."[261] Purdue's statement on "Opioids Corporate Responsibility" likewise states that "[f]or many years, Purdue has committed substantial resources to combat opioid abuse by partnering with . . . communities, law enforcement, and government."[262] And, responding to criticism of Purdue's failure to report suspicious prescribing to government regulatory and enforcement authorities, the website similarly proclaims that Purdue "ha[s] a long record of close coordination with the DEA and other law enforcement stakeholders to detect and reduce drug diversion."[263]

573. These public pronouncements create the false impression that Purdue is proactively working with law enforcement and government authorities nationwide to root out drug diversion, including the illicit prescribing that can lead to diversion. It aims to distance Purdue from its past

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Programs (July 11, 2016), http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/.

[261] Purdue website, *Opioids With Abuse-Deterrent Properties*, http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/ (last accessed Aug. 1, 2018).

[262] *Id.*

[263] Purdue, *Setting The Record Straight On Our Anti-Diversion Programs* (July 11, 2016), available at http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straighton-our-anti-diversion-programs/. Contrary to its public statements, Purdue seems to have worked behind the scenes to push back against law enforcement.

conduct in deceptively marketing opioids and make its current marketing seem more trustworthy and truthful.

574. Public statements by the Defendants and their associates created the false and misleading impression to regulators, prescribers, and the public that the Defendants rigorously carried out their legal duties, including their duty to report suspicious orders and exercise due diligence to prevent diversion of these dangerous drugs, and further created the false impression that these Defendants also worked voluntarily to prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

8. The Distributor Defendants Breached Their Duties

575. Because distributors are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on them to maintain effective controls to prevent diversion of controlled substances.

576. The sheer volume of prescription opioids distributed to pharmacies in various areas, and/or to pharmacies from which the Distributor Defendants knew the opioids were likely to be diverted, was excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.[264]

577. The Distributor Defendants failed to report "suspicious orders," which the Distributor Defendants knew were likely to be diverted, to the relevant governmental authorities.

578. The Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern, and/or orders of unusual frequency, and/or in

[264] *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418-01, 55,482 (Sept. 15, 2015) (citing *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy*, Nos. 219 and 5195, 77 Fed. Reg. 62,316, 62,322 (2012)).

areas from which the Distributor Defendants knew opioids were likely to be diverted.

579. The Distributor Defendants breached their duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted.

580. The Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels.

581. The Distributor Defendants breached their duty to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and failed to inform the authorities, including the DEA, of suspicious orders when discovered in violation of their duties under Kentucky law.

582. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific, and industrial channels.[265]

583. The laws at issue here concerning the sale and distribution of controlled substances are also Kentucky public safety laws.

584. The Distributor Defendants' violations of public safety statutes constitute *prima facie* evidence of negligence under State law.

585. The unlawful conduct by the Distributor Defendants is purposeful and intentional. The Distributor Defendants refuse to abide by the duties imposed by Kentucky law which are required to legally acquire and maintain a license to distribute prescription opiates.

586. The Distributor Defendants acted with actual malice in breaching their duties, i.e.,

[265] *See Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

they have acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

587. The Distributor Defendants' repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authoritie,s demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.

a. Cardinal

588. To date, Cardinal has paid a total of $98 million in fines and other amounts involving multiple DEA and various state actions relating to its improper management and distribution of opioids to pharmacies across the United States.

589. In 2008, Cardinal paid a $34 million penalty to settle allegations about opioid diversion taking place at seven warehouses[266] around the United States (the "2008 Cardinal Settlement Agreement").[267] These allegations included failing to report to the DEA thousands of

[266] Including its Lakeland, Florida facility. https://www.dea.gov/pubs/pressrel/pr100608.html. In 2012, Cardinal described the Lakeland facility as shipping "an average of about 4 million dosage units of prescription drugs, including about 500,000 dosage units of controlled substances, on a monthly basis to more than 5,200 customers in Florida, Georgia and South Carolina. The volume of prescription drugs distributed makes the Lakeland facility the largest prescription drug wholesaler in Florida." *Cardinal Health, Inc. v. Eric Holder, Jr., Att'y Gen.*, D.D.C. Case No. 12-185, ECF No. 3-1, at 6; 3-13 at 2; 3-15 (Feb. 3, 2012).

[267] Settlement and Release Agreement and Administrative Memorandum of Agreement (Sept. 30, 2008), a cached version is *available at* https://webcache.googleusercontent.com/search?q=cache:O7Te0HbVfpIJ:https://www.dea.gov/divisions/hq/2012/cardinal_agreement.pdf+&cd=2&hl=en&ct=clnk&gl=us; Press Release, U.S. Att'y Office, Dist. of Colo., Cardinal Health Inc., Agrees to Pay $34 Million to Settle Claims that it Failed to Report Suspicious Sales of Widely-Abused Controlled Substances (Oct. 2, 2008), https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html.

suspicious orders of hydrocodone that Cardinal then distributed to pharmacies that filled illegitimate prescriptions originating from rogue Internet pharmacy websites.[268]

590. In connection with the 2008 Cardinal Settlement Agreement, the DEA stated that "[d]espite [its] repeated attempts to educate Cardinal on diversion awareness and prevention, Cardinal engaged in a pattern of failing to report blatantly suspicious orders for controlled substances filled by its distribution facilities located throughout the United States."[269] The DEA concluded that "Cardinal's conduct allowed the 'diversion' of millions of dosage units of hydrocodone from legitimate to non-legitimate channels."[270]

591. As part of the 2008 Cardinal Settlement Agreement, Cardinal agreed to "maintain a compliance program designed to detect and prevent diversion of controlled substances as required by the CSA and applicable DEA regulations."[271] However, in 2012, the DEA issued an "immediate suspension order," suspending Cardinal's registration with respect to Cardinal's drug distribution facility in Lakeland, Florida. That order stated that "Despite the [2008 Cardinal Settlement Agreement], the specific guidance provided to Cardinal by DEA, and despite the public information readily available regarding the oxycodone epidemic in Florida, Cardinal has failed to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, and industrial channels, in violation of [the CSA]."[272] For example, from "2008-2009, Cardinal's sales to its top four retail pharmacies [in the State of Florida] increased

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[268] *Id.*
[269] U.S. Att'y Office, Dist. of Colo., *Cardinal Health Inc. Agrees to Pay $34 Million to Settle Claims that It Failed to Report Suspicious Sales of Widely-Abused Controlled Substances* (Oct. 2, 2008), https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html.
[270] *Id.*
[271] *Cardinal Health, Inc. v. Eric Holder, Jr., Att'y Gen.*, D.D.C. Case No. 12-185, ECF No. 3-4, at ¶ 2 (Feb. 3, 2012).
[272] *Id*. at ¶ 3.

approximately 803%. From 2009 to 2010, Cardinal's sales to its top four retail pharmacies [in the State of Florida] increased 162%."[273]

592. In 2012, Cardinal reached another settlement with the DEA relating to its failure to "conduct meaningful due diligence to ensure that the controlled substances were not diverted into other than legitimate channels" resulting in systemic opioid diversion in its Florida distribution center (the "2012 Cardinal Settlement Agreement").[274] Cardinal's Florida center received a two-year license suspension for supplying more than 12 million dosage units to only four area pharmacies, nearly fifty times as much oxycodone as it shipped to the rest of Florida and an increase of 241% in only two years.[275] The DEA found that Cardinal's own investigator warned Cardinal against selling opioids to these pharmacies, but that Cardinal did nothing to notify the DEA or cut off the supply of drugs to the suspect pharmacies.[276] Instead, Cardinal's opioid shipments to the pharmacies increased.[277]

593. In the 2012 Cardinal Settlement Agreement, Cardinal agreed that it had (i) failed to maintain effective controls against the diversion of controlled substances, including failing to conduct meaningful due diligence to ensure that controlled substances were not diverted; (ii) failed to detect and report suspicious orders of controlled substances as required by the CSA, on or before May 14, 2012; and (iii) failed to adhere to the provisions of the 2008 Cardinal Settlement

[273] *Id*. at ¶ 4.
[274] Administrative Memorandum of Agreement (May 14, 2012), https://www.dea.gov/divisions/hq/2012/cardinal_agreement.pdf (last accessed August 1, 2018); Press Release, Drug Enf't Admin., DEA Suspends for Two Years Pharmaceutical Wholesale Distributor's Ability to Sell Controlled Substances from Lakeland, Florida Facility (May 15, 2012), https://www.dea.gov/pubs/pressrel/pr051512.html.
[275] *Id.*
[276] *Id.*
[277] *Id.*

Agreement.[278]

594. In December 2016, Cardinal again settled charges that it had violated the CSA by failing to prevent diversion of oxycodone for illegal purposes, this time for $44 million (the "2016 Cardinal Settlement Agreement").[279] The settlement covered DEA allegations that Cardinal had failed to report suspicious orders across Washington, Maryland, New York, and Florida.[280] The same Florida distribution center at the heart of the 2012 settlement was again implicated in this case.[281] The settlement also covered a Cardinal subsidiary, Kinray, LLC, which failed to report a single suspicious order despite shipping oxycodone and hydrocodone to more than 20 New York-area pharmacy locations that placed unusually high orders of controlled substances at an unusually frequent rate.[282]

b. AmerisourceBergen

595. AmerisourceBergen has paid $16 million in settlements and had certain licenses revoked as a result of allegations related to the diversion of prescription opioids.

596. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies.[283] Over the course of one year, AmerisourceBergen had distributed 3.8

[278] Administrative Memorandum of Agreement (May 14, 2012), https://www.dea.gov/divisions/hq/2012/cardinal_agreement.pdf (last accessed August 1, 2018).
[279] U.S. Att'y Office, Dist. of Md., *Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act* (Dec. 23, 2016), https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act.
[280] *Id.*
[281] *Id.*
[282] *Id.*
[283] Press Release, Drug Enf't Admin., *DEA Suspends Orlando Branch of Drug Company from Distributing Controlled Substances* (Apr. 24, 2007), https://www.dea.gov/divisions/mia/2007/mia042407p.html.

million dosage units of hydrocodone to "rogue pharmacies."[284] The DEA suspended AmerisourceBergen's registration after determining that "the continued registration of this company constitutes an imminent danger to public health and safety."[285]

597. Again in 2012, AmerisourceBergen was implicated for failing to protect against diversion of particular controlled substances into non-medically necessary channels.[286]

9. The Distributor Defendants Have Sought to Avoid and Have Misrepresented Their Compliance with Their Legal Duties

598. The Distributor Defendants have repeatedly misrepresented their compliance with their legal duties under Kentucky law and have wrongfully and repeatedly disavowed those duties in an effort to mislead regulators and the public regarding the Distributor Defendants' compliance with their legal duties.

599. Distributor Defendants have refused to recognize any duty beyond reporting suspicious orders. In *Masters Pharm., Inc. v. Drug Enf't Admin*., 861 F.3d 206 (D.C. Cir. 2017), the Healthcare Distribution Management Association, n/k/a HDA, a trade association run by the Distributor Defendants, and the National Association of Chain Drug Stores ("NACDS") submitted amicus briefs regarding the legal duty of wholesale distributors. Inaccurately denying the legal duties that the wholesale drug industry has been tragically recalcitrant in performing, they argued as follows:

a. The Associations complained that the "DEA has required distributors not only to report suspicious orders, but to *investigate* orders (e.g., by interrogating

[284] *Id.*
[285] *Id.*
[286] Jeff Overley, *AmerisourceBergen Subpoenaed by DEA Over Drug Diversion,* Law360.com (Aug. 9, 2012), *available at* https://www.law360.com/articles/368498/amerisourcebergen-subpoenaed-by-dea-over-drug-diversion.

pharmacies and physicians) and take action to *halt* suspicious orders before they are filled."[287]

b. The Associations argued that, "DEA now appears to have changed its position to require that distributors not only *report* suspicious orders, but *investigate* and *halt* suspicious orders. Such a change in agency position must be accompanied by an acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it *is* changing position and show that there are good reasons for the new policy. This is especially important here, because imposing intrusive obligation on distributors threatens to disrupt patient access to needed prescription medications."[288]

c. The Associations alleged (inaccurately) that nothing "requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious."[289]

d. The Associations complained that the purported "practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties."[290]

[287] Brief for HDMA and NACDS, *supra* n. 246, 2016 WL 1321983, at *4–5.
[288] *Id.* at *8 (citations and quotation marks omitted).
[289] *Id.* at *14.
[290] *Id.* at *22.

e. The Associations alleged (inaccurately) that "DEA's regulations [ ] sensibly impose[] a duty on distributors simply to *report* suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders."[291]

f. Also inaccurately, the Associations argued that, "[i]mposing a duty on distributors – which lack the patient information and the necessary medical expertise – to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA's demands."[292]

600. The positions taken by the trade groups is emblematic of the position taken by the Distributor Defendants in a futile attempt to deny their legal obligations to prevent diversion of the dangerous drugs.[293]

601. The Court of Appeals for the District of Columbia recently issued its opinion affirming that a wholesale drug distributor does, in fact, have duties beyond reporting. In *Masters Pharmaceuticals*, the Court upheld the revocation of Masters Pharmaceutical's license and determined that DEA regulations require that in addition to reporting suspicious orders, distributors must "decline to ship the order, or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order." Masters Pharmaceutical was in violation of legal requirements because it failed to conduct necessary investigations and filled suspicious orders. A distributor's investigation must dispel all the red flags giving rise to suspicious circumstance prior to shipping a suspicious order. The Circuit Court also rejected the argument made by the HDMA and NACDS (quoted above), that, allegedly, the

[291] *Id.* at *24–25
[292] *Id.* at 26.
[293] *See* Brief of HDMA in Support of Cardinal, *supra* n. 255, 2012 WL 1637016, at *3 (arguing the wholesale distributor industry "does not know the rules of the road because" they claim (inaccurately) that the "DEA has not adequately explained them").

DEA had created or imposed new duties.

602. Because of the Distributor Defendants' refusals to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. For example, in May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012.[294] As noted above, the Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.[295] These actions include the following:

a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

[294] Evaluation and Inspections Div., Off. of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* (May 2014), https://oig.justice.gov/reports/2014/e1403.pdf.
[295] *Id.*

c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On September 30, 2008, Cardinal entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

g. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Lakeland, Florida Distribution Center

("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone; and

h. On December 23, 2016, Cardinal agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center.

603. Rather than abide by their non-delegable duties under public safety laws, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension order can be issued.[296]

604. In addition to taking actions to limit regulatory prosecutions and suspensions, the Distributor Defendants undertook to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such

[296] *See* Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, WASHINGTON POST (Oct. 22, 2016), https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.2f757833e3c4; Lenny Bernstein & Scott Higham, *Investigations: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, WASHINGTON POST (Mar. 6, 2017), https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html?utm_term=.7007bf2b9455; Eric Eyre, *DEA Agent: "We Had No Leadership" in WV Amid Flood of Pain Pills*, CHARLESTON GAZETTE-MAIL (Feb. 18, 2017), https://www.wvgazettemail.com/news/health/dea-agent-we-had-no-leadership-in-wv-amid-flood/article_928e9bcd-e28e-58b1-8e3f-f08288f539fd.html.

statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

605. For example, a Cardinal executive claimed that it uses "advanced analytics" to monitor its supply chain and represented that it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[297] Given the sales volumes and the company's history of violations, this executive was either not telling the truth, or, if Cardinal had such a system, it ignored the results.

606. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that the Plaintiff now asserts.

607. Meanwhile, the opioid epidemic rages unabated in the United States and Kentucky.

608. The epidemic still rages because the fines and suspensions imposed by the DEA do not change the conduct of the industry. The distributors, including the Distributor Defendants, pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility.

609. The wrongful actions and omissions of the Distributor Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiff's allegations of Defendants' unlawful acts below.

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[297] Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: "No One Was Doing Their Job,"* WASHINGTON POST (Oct. 22, 2016), https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?utm_term=.a5f051722a7a.

610. The Distributor Defendants have abandoned their duties imposed under Kentucky law, taken advantage of a lack of adequate law enforcement, and abused the privilege of distributing controlled substances.

M. The Marketing Defendants' Unlawful Failure to Prevent Diversion and Monitor, Report, and Prevent Suspicious Orders

611. The same legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids that were incumbent upon the Distributor Defendants were also legally required of the Marketing Defendants under Kentucky law. Like the Distributor Defendants, the Marketing Defendants were required to register with the Kentucky Board of Pharmacy and the DEA to manufacture Schedule II controlled substances, like prescription opioids. *See* KRS 218A.010(10), (11), (12), (38); KRS 218A.150(1) (repealed 2018); KRS 218A.170(1), (2); KRS 315.010, *et seq*; KRS 315.400 *et seq*; and 201 KAR 2:230. Under Kentucky state law, it has been declared that "[t]he regulation of controlled substances in this Commonwealth is important and necessary for the preservation of public safety and public health." KRS 218A.005(1).

612. Kentucky state law requires that a "manufacturer, distributor, or wholesaler" must comply with "KRS 218A.200 and the federal controlled substances laws." KRS 218A.170.

613. Pursuant to KRS 218A.200, manufacturers and wholesalers of opioids "shall keep records of all controlled substances compounded, mixed, cultivated, grown, or by any other process produced or prepared, and all of controlled substances received and disposed of by them."

614. Defendants violated both Kentucky state law and the federal Controlled Substances Act in failing to report suspicious orders of opioid pain medications in Kentucky. Defendants violated state and federal law in failing to maintain effective controls against the diversion of opioids into other than legitimate medical channels. Defendants also violated state and federal law

in failing to operate a system to stop orders which is flagged or should have been flagged as suspicious.

615. Each Defendant's actions were in violation of Chapter 218A of the Kentucky Revised Statutes, as set out above, and 218A.1404(3), which forbids unlawful distribution of controlled substances; KRS 218A.1404 (1), which forbids the trafficking of controlled substances; KRS 506.040 and KRS 218A.1402, which forbid criminal drug conspiracies; and KRS 218A.1405, which forbids receipt of income from trafficking and utilizing that income to operate a commercial enterprise.[298]

616. Like the Distributor Defendants, the Marketing Defendants breached these duties.

617. The Marketing Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The Marketing Defendants engaged in the practice of paying "chargebacks" to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Marketing Defendants knew – just as the

[298] Defendants also violated provisions of the West Virginia Controlled Substances Act (the "WVCSA"), W.Va. Code §§ 60A-4-401 through 403, which describe prohibited acts under the law and penalties for those acts. The statute makes it unlawful, for example, for any person "[w]ho is subject to article 3 to distribute or dispense a controlled substance in violation of section [60A-3-] 308." W. Va. Code § 60A-4-402(a)(1). Section 60A-3-308 of the WVCSA governs distribution of controlled substances, which is prohibited except by prescription. It provides, for example, that substances included in certain schedules of the law "shall not be distributed or dispensed other than for a medicinal purpose." W. Va. Code § 60A-3-308(d)(1). Defendants also violated West Virginia's Wholesale Drug Distribution Licensing Act of 1991, W.Va. Code § 60A-8-1 et seq. The WVDDLA governs persons engaged in the "wholesale distribution of human prescription drugs within [West Virginia]." W. Va. Code § 60A-8-2.

Distributor Defendants knew – the volume, frequency, and pattern of opioid orders being placed and filled. The Marketing Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

618. Federal and Kentucky statutes and regulations are clear: just like opioid distributors, opioid manufacturers are required to "design and operate a system to disclose . . . suspicious orders of controlled substances" and to maintain "effective controls against diversion." 21 C.F.R. § 1301.74; 21 USCA § 823(a)(1); *see also* KRS 218A.010, *et seq*. ("Kentucky Uniform Controlled Substances Act").[299]

619. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by federal law upon opioid manufacturers, fining Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.[300]

620. In the press release accompanying the settlement, the Department of Justice stated:

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[299] West Virginia regulations are to similar effect. West Virginia Code of State Rules ("W.V.C.S.R.") 15-2-4.2.1 states as follows:

> All registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the [West Virginia] Board [of Pharmacy] shall evaluate the overall security system and needs of the applicant or registrant.

W. Va. C.S.R. 15-2-4.2.1. Rule 15-2-4.4 further requires as follows:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Office of the Board of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

W. Va. C.S.R. 15-2-4.4. Defendants failed to comply with these requirements.

[300] *See* Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

"[Mallinckrodt] did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone." . . . "Mallinckrodt's actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. . . . Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands. . . ."[301]

621. Among the allegations resolved by the settlement, the government alleged "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances – orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."[302]

622. The Memorandum of Agreement entered into by Mallinckrodt (2017 Mallinckrodt MOA") avers "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."[303] Mallinckrodt further stated that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and agreed that it would "design and operate a system that meets the requirements of 21 C.F.R. §

[301] *Id.*
[302] *Id.*
[303] Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin., and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC (July 10, 2017), https://www.justice.gov/usao-edmi/press-release/file/986026/download ("2017 Mallinckrodt MOA").

1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product." Mallinckrodt specifically agreed "to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."

623. The 2017 Mallinckrodt MOA further details the DEA's allegations regarding Mallinckrodt's failures to fulfill its legal duties as an opioid manufacturer:

a. With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt's alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt's alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt's alleged failure to: conduct adequate due diligence of its customers;

b. Detect and report to the DEA orders of unusual size and frequency;

c. Detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:

    i. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,

    ii. orders that purchased a disproportionate amount of substance which is most often abused compared to other products, and

iii. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware;

d. Use "chargeback" information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and

e. Take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.[304]

624. Mallinckrodt agreed that its "system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007." Mallinckrodt further agreed that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and would "design and operate a system that meets the requirements of 21 C.F.R. 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product. Further, Mallinckrodt agrees to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."[305]

625. Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers

[304] *Id.* at 2-3.
[305] *Id.* at 3-4.

(distributors). The transaction information contains data relating to the direct customer sales of controlled substances to 'downstream' registrants." Mallinckrodt agreed that, from this data, it would "report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion."[306]

626. The same duties imposed by federal law on Mallinckrodt were imposed upon all Marketing Defendants.

627. The same business practices utilized by Mallinckrodt regarding "charge backs" and receipt and review of data from opioid distributors regarding orders of opioids were utilized industry-wide among opioid manufacturers and distributors, including the other Marketing and Distributor Defendants.

628. Through, *inter alia*, the charge back data, the Marketing Defendants could monitor suspicious orders of opioids.

629. The Marketing Defendants failed to monitor, report, and halt suspicious orders of opioids as required by federal and Kentucky law.

630. The Marketing Defendants' failures to monitor, report, and halt suspicious orders of opioids were intentional and unlawful.

631. The Marketing Defendants have misrepresented their compliance with federal and Kentucky law.

632. The wrongful actions and omissions of the Marketing Defendants that caused the diversion of opioids and which were a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiff's allegations of Defendants' unlawful acts below.

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[306] *Id.* at 5.

633. The Marketing Defendants' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids throughout the United States.

N. Defendants' Unlawful Conduct and Breaches of Legal Duties Caused the Harm and Substantial Damage Alleged Herein

634. As the Marketing Defendants' efforts to expand the market for opioids increased so have the rates of prescription and sale of their products — and the rates of opioid-related substance abuse, hospitalization, and death among the people of the United States, including Kentucky. The Distributor Defendants have continued to unlawfully ship these massive quantities of opioids.

635. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[307]

636. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.[308]

637. The epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[309]

638. The increased abuse of prescription painkillers along with growing sales has contributed to a large number of overdoses and deaths.[310]

639. One doctor, for example in Ohio, was convicted of illegally distributing some

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[307] *See* Richard C. Dart et al, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241-248 (2015), DOI: 10.1056/NEJMsa1406143, http://www.nejm.org/doi/full/10.1056/NEJMsa1406143.
[308] *See* Volkow & McLellan, *supra* n. 53.
[309] *See* Califf, *et al.*, *supra*.
[310] *See* Press Release, Centers for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *supra*.

30,000 tablets of oxycodone, OxyContin, and Opana. In connection with sentencing, the U.S. Attorney explained that its enforcement efforts reflected that "[o]ur region is awash in opioids that have brought heartbreak and suffering to countless families." Henry Schein delivered opioids directly to the office of this doctor, whom the Northern District of Ohio court has described as "selling 30,000 doses of poison into the community."[311] In a separate civil suit, the same prescriber reached a consent judgment in a civil suit alleging that he was purchasing hydrocodone/APAP tablets (hydrocodone and acetaminophen), from Henry Schein on as many as fourteen separate dates within a one-year period, and, subsequently dispensed 11,500 hydrocodone tablets without maintaining purchase and dispensing records as required by the CSA.

640. As shown above, the opioid epidemic has escalated with devastating effects: substantial opiate-related substance abuse, hospitalization, and death that goes hand in hand with Defendants' increased distribution of opioids.

641. Because of the well-established relationship between the use of prescription opioids and the use of non-prescription opioids, like heroin, the massive distribution of opioids by Defendants has caused the opioid epidemic to include heroin addiction, abuse, and death.

642. Defendants repeatedly and purposefully breached their duties under federal and Kentucky law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for nonmedical purposes and the foreseeable, inevitable financial burdens imposed on and incurred by hospitals, health departments, and other health care providers.

643. The unlawful diversion of prescription opioids is a direct and proximate cause of,

[311] Eric Heisig, *Former Akron-Area Doctor Sentenced to 63 Months in Prison for Doling Out Painkillers*, Cleveland.com (Mar. 16, 2015), https://www.cleveland.com/court-justice/index.ssf/2015/03/former_akron-area_doctor_sente.html.

and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction, morbidity, and mortality in the United States. This diversion and the epidemic are direct causes of foreseeable harm to Plaintiff.

644. Defendants' unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages for which Plaintiff seeks relief.

O. Conspiracy Allegations

1. The Defendants Conspired To Engage In The Wrongful Conduct Complained Of Herein and Intended To Benefit Both Independently and Jointly From Their Conspiracy

a. Conspiracy Among Marketing Defendants

645. The Marketing Defendants agreed among themselves to set up, develop, and fund an unbranded promotion and marketing network to promote the use of opioids for the management of pain in order to mislead physicians, patients, health care providers such as hospitals, and health care payors through misrepresentations and omissions regarding the appropriate uses, risks, and safety of opioids in order to increase sales, revenue, and profit from their opioid products.

646. This interconnected and interrelated network relied on the Marketing Defendants' collective use of unbranded marketing materials, such as KOLs, scientific literature, CMEs, patient education materials, and Front Groups developed and funded collectively by the Marketing Defendants and intended to mislead consumers and medical providers, such as hospitals, of the appropriate uses, risks, and safety of opioids.

647. The Marketing Defendants' collective marketing scheme to increase opioid prescriptions, sales, revenues and profits centered around the development, dissemination, and reinforcement of nine false propositions: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition dubbed

"pseudoaddiction"; (4) that withdrawal is easily managed; (5) that increased dosing presents no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse.

648. The Marketing Defendants knew that none of these propositions are true.

649. Each Marketing Defendant worked individually and collectively to develop and actively promulgate these nine false propositions in order to mislead physicians, patients, and health care providers such as hospitals, health departments, and healthcare payors regarding the appropriate uses, risks, and safety of opioids.

650. What is particularly remarkable about the Marketing Defendants' effort is the seamless method in which the Marketing Defendants joined forces to achieve their collective goal: to persuade consumers and medical providers, such as hospitals, of the safety of opioids, and to hide their actual risks and dangers. In doing so, the Marketing Defendants effectively built a new – and extremely lucrative – opioid marketplace for their select group of industry players.

651. The Marketing Defendants' unbranded promotion and marketing network was a wildly successful marketing tool that achieved marketing goals that would have been impossible to have been met by a single or even a handful of the network's distinct corporate members.

652. For example, the network members pooled their vast marketing funds and dedicated them to expansive and normally cost-prohibitive marketing ventures, such as the creation of Front Groups. These collaborative networking tactics allowed each Marketing Defendant to diversify its marketing efforts, all the while sharing any risk and exposure, financial and/or legal, with other Marketing Defendants

653. The most unnerving tactic utilized by the Marketing Defendants' network was their unabashed mimicry of the scientific method of citing "references" in their materials. In the scientific community, cited materials and references are rigorously vetted by objective unbiased and disinterested experts in the field, and an unfounded theory or proposition would, or should, never gain traction.

654. Marketing Defendants put their own twist on the scientific method: they worked together to manufacture wide support for their unfounded theories and propositions involving opioids. Due to their sheer numbers and resources, the Marketing Defendants were able to create a false consensus through their materials and references.

655. An illustrative example of the Marketing Defendants' utilization of this tactic is the wide promulgation of the Porter & Jick Letter, which declared the incidence of addiction "rare" for patients treated with opioids. The authors had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. These patients were not given long-term opioid prescriptions or provided opioids to administer to themselves at home, nor was it known how frequently or infrequently and in what doses the patients were given their narcotics. Rather, it appears the patients were treated with opioids for short periods of time under in-hospital doctor supervision.

656. Nonetheless, Marketing Defendants widely and repeatedly cited this letter as proof of the low addiction risk in connection with taking opioids despite the letter's obvious shortcomings. Marketing Defendants' egregious misrepresentations based on this letter included claims that less than one percent of opioid users became addicted.

657. Marketing Defendants' collective misuse of the Porter & Jick Letter helped the opioid manufacturers convince patients and healthcare providers such as hospitals that opioids

were not a concern. The enormous impact of Marketing Defendants' misleading amplification of this letter was well documented in another letter published in the NEJM on June, 1, 2017, describing the way the one-paragraph 1980 letter had been irresponsibly cited and, in some cases, "grossly misrepresented." In particular, the authors of this letter explained:

658. [W]e found that a five-sentence letter published in the Journal in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crises by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy…

659. By knowingly misrepresenting the appropriate uses, risks, and safety of opioids, the Marketing Defendants committed overt acts in furtherance of their conspiracy.

b. Conspiracy Among All Defendants

660. In addition, and on an even broader level, all Defendants took advantage of the industry structure, including end-running its internal checks and balance, to their collective advantage. Defendants agreed among themselves to increase the supply of opioids and fraudulently increase the quotas that governed the manufacture and supply of prescription opioids. Defendants did so to increase sales, revenue, and profit from their opioid products.

661. The interaction and length of the relationships between and among the Defendants reflects a deep level of interaction and cooperation between Defendants in a tightly knit industry. The Marketing and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

662. Defendants collaborated to expand the opioid market in an interconnected and interrelated network in the following ways, as set forth more fully below including, for example, membership in the Healthcare Distribution Alliance.

663. Defendants utilized their membership in the HDA and other forms of collaboration to form agreements about their approach to their duties under the CSA to report suspicious orders. The Defendants overwhelmingly agreed on the same approach – to fail to identify, report, or halt suspicious opioid orders, and fail to prevent diversion. Defendants' agreement to restrict reporting provided an added layer of insulation from DEA scrutiny for the entire industry as Defendants were thus collectively responsible for each other's compliance with their reporting obligations. Defendants were aware, both individually and collectively, of the suspicious orders that flowed directly from Defendants' facilities.

664. Defendants knew that their own conduct could be reported by other Defendants and that their failure to report suspicious orders they filled could be brought to the DEA's attention. As a result, Defendants had an incentive to communicate with each other about the reporting or suspicious orders to ensure consistency in their dealings with DEA.

665. The Defendants also worked together to ensure that the opioid quotas allowed by the DEA remained artificially high and ensured that suspicious orders were not reported to the DEA in order to ensure that the DEA had no basis for refusing to increase or decrease production quotas due to diversion.

666. The desired consistency and collective end goal was achieved. Defendants achieved blockbuster profits through higher opioid sales by orchestrating the unimpeded flow of opioids.

2. Additional Facts Pertaining to Punitive Damages

667. As set forth above, Defendants acted deliberately to increase sales of, and profits from, opioid drugs. The Marketing Defendants knew there was no support for their claims that

addiction was rare, that addiction risk could be effectively managed, that signs of addiction were merely "pseudoaddiction," that withdrawal is easily managed, that higher doses pose no significant additional risks, that long-term use of opioids improves function, or that time-release or abuse-deterrent formulations would prevent addiction or abuse. Nonetheless, they knowingly promoted these falsehoods in order to increase the market for their addictive drugs.

668. All of the Defendants, moreover, knew that large and suspicious quantities of opioids were being poured into communities throughout the United States. Despite this knowledge, Defendants took no steps to report suspicious orders, control the supply of opioids, or otherwise prevent diversion. Indeed, as described above, Defendants acted in concert together to maintain high levels of quotas for their products and to ensure that suspicious orders would not be reported to regulators.

669. Defendants' conduct was so willful and deliberate that it continued in the face of numerous enforcement actions, fines, and other warnings from state and local governments and regulatory agencies. Defendants paid their fines, made promises to do better, and continued on with their marketing and supply schemes. This ongoing course of conduct knowingly, deliberately, and repeatedly threatened and accomplished harm and risk of harm to public health and safety, and large-scale economic loss to communities, governments, families, communities, hospitals and health care providers across the country.

670. As all of the governmental actions against the Marketing Defendants and against all the Defendants show, Defendants knew that their actions were unlawful, and yet deliberately refused to change their practices because compliance with their legal obligations would have decreased their sales and their profits.

a. The Marketing Defendants Persisted in Their Fraudulent Scheme Despite Repeated Admonitions, Warnings, and Even Prosecutions

671. So determined were the Marketing Defendants to sell more opioids that they simply ignored multiple admonitions, warnings, and prosecutions, as described more fully below.

i. FDA Warnings to Janssen Failed to Deter Janssen's Misleading Promotion of Duragesic

672. On February 15, 2000, the FDA sent Janssen a letter concerning the dissemination of "homemade" promotional pieces that promoted the Janssen drug Duragesic in violation of the Federal Food, Drug, and Cosmetic Act. In a subsequent letter, dated March 30, 2000, the FDA explained that the "homemade" promotional pieces were "false or misleading because they contain misrepresentations of safety information, broaden Duragesic's indication, contain unsubstantiated claims, and lack fair balance." The March 30, 2000 letter detailed numerous ways in which Janssen's marketing was misleading.

673. The letter did not stop Janssen. On September 2, 2004, the U.S. Department of Health and Human Services ("HHS") sent Janssen a warning letter concerning Duragesic due to "false or misleading claims about the abuse potential and other risks of the drug, and . . . unsubstantiated effectiveness claims for Duragesic," including, specifically, "suggesting that Duragesic has a lower potential for abuse compared to other opioid products." The September 2, 2004 letter detailed a series of unsubstantiated, false or misleading claims.

674. One year later, Janssen was still at it. On July 15, 2005, the FDA issued a public health advisory warning doctors of deaths resulting from the use of Duragesic and its generic competitor, manufactured by Mylan N.V. The advisory noted that the FDA had been "examining the circumstances of product use to determine if the reported adverse events may be related to inappropriate use of the patch" and noted the possibility "that patients and physicians might be unaware of the risks" of using the fentanyl transdermal patch, which is a potent opioid analgesic

approved only for chronic pain in opioid-tolerant patients that could not be treated by other drugs.

ii. Governmental Action, Including Large Monetary Fines, Failed to Stop Cephalon From Falsely Marketing Actiq For Off-label Uses

675. On September 29, 2008, Cephalon finalized and entered into a corporate integrity agreement with the Office of the Inspector General of HHS and agreed to pay $425 million in civil and criminal penalties for its off-label marketing of Actiq and two other drugs (Gabitril and Provigil). According to a DOJ press release, Cephalon had trained sales representatives to disregard restrictions of the FDA-approved label, employed sales representatives and healthcare professionals to speak to physicians about off-label uses of the three drugs and funded CMEs to promote off-label uses.

676. Notwithstanding letters, an FDA safety alert, DOJ and state investigations, and the massive settlement, Cephalon has continued its deceptive marketing strategy.

iii. FDA Warnings Did Not Prevent Cephalon from Continuing False and Off-Label Marketing of Fentora

677. On September 27, 2007, the FDA issued a public health advisory to address numerous reports that patients who did not have cancer or were not opioid tolerant had been prescribed Fentora, and death or life-threatening side effects had resulted. The FDA warned: "Fentora should not be used to treat any type of short-term pain." Indeed, the FDA specifically denied Cephalon's application, in 2008, to broaden the indication of Fentora to include treatment of non-cancer breakthrough pain and use in patients who were not already opioid-tolerant.

678. Flagrantly disregarding the FDA's refusal to broaden the indication for Fentora, Cephalon nonetheless marketed Fentora beyond its approved indications. On March 26, 2009, the FDA warned Cephalon against its misleading advertising of Fentora ("Warning Letter"). The Warning Letter described a Fentora Internet advertisement as misleading because it purported to

broaden "the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora . . . when this is not the case." It further criticized Cephalon's other direct Fentora advertisements because they did not disclose the risks associated with the drug.

679. Despite this warning, Cephalon continued to use the same sales tactics to push Fentora as it did with Actiq. For example, on January 13, 2012, Cephalon published an insert in Pharmacy Times titled "An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate)." Despite the repeated warnings of the dangers associated with the use of the drugs beyond their limited indication, as detailed above, the first sentence of the insert states: "It is well recognized that the judicious use of opioids can facilitate effective and safe management of chronic pain."

iv. A Guilty Plea and a Large Fine did not Deter Purdue from Continuing its Fraudulent Marketing of OxyContin

680. In May 2007, Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin in what the company acknowledged was an attempt to mislead doctors about the risk of addiction. Purdue was ordered to pay $600 million in fines and fees. In its plea, Purdue admitted that its promotion of OxyContin was misleading and inaccurate, misrepresented the risk of addiction, and was unsupported by science. Additionally, Michael Friedman, the company's president, pled guilty to a misbranding charge and agreed to pay $19 million in fines; Howard R. Udell, Purdue's top lawyer, also pled guilty and agreed to pay $8 million in fines; and Paul D. Goldenheim, its former medical director, pled guilty as well and agreed to pay $7.5 million in fines.

681. Nevertheless, even after the settlement, Purdue continued to pay doctors on speakers' bureaus to promote the liberal prescribing of OxyContin for chronic pain and to fund

seemingly neutral organizations to disseminate the message that opioids were non-addictive as well as other misrepresentations. At least until early 2018, Purdue continued deceptively marketing the benefits of opioids for chronic pain while diminishing the associated dangers of addiction. After Purdue made its guilty plea in 2007, it assembled an army of lobbyists to fight any legislative actions that might encroach on its business. Between 2006 and 2015, Purdue and other painkiller producers, along with their associated nonprofits, spent nearly $900 million dollars on lobbying and political contributions - eight times what the gun lobby spent during that period.

682. Since at least 2002, Purdue has maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids. Physicians could be added to this database based on observed indicators of illicit prescribing such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing of the highest-strength pills (80 mg OxyContin pills or "80s," as they were known on the street, were a prime target for diversion). Purdue claims that health care providers added to the database no longer were detailed, and that sales representatives received no compensation tied to these providers' prescriptions.

683. Yet, Purdue failed to cut off these providers' opioid supply at the pharmacy level—meaning Purdue continued to generate sales revenue from their prescriptions—and failed to report these providers to state medical boards or law enforcement. Purdue's former senior compliance officer acknowledged in an interview with the Los Angeles Times that in five years of investigating suspicious pharmacies, the company never stopped the supply of its opioids to a pharmacy, even where Purdue employees personally witnessed the diversion of its drugs.

684. The same was true of prescribers. For example, as discussed above, despite Purdue's knowledge of illicit prescribing from one Los Angeles clinic which its district manager called an "organized drug ring" in 2009, Purdue did not report its suspicions until long after law

enforcement shut it down and not until the ring prescribed more than 1.1 million OxyContin tablets.

685. Indeed, the New York Attorney General found that Purdue placed 103 New York health care providers on its "No-Call" List between January 1, 2008 and March 7, 2015, and that Purdue's sales representatives had detailed approximately two-thirds of these providers, some quite extensively, making more than a total of 1,800 sales calls to their offices over a six-year period.

v. Endo Continued to Aggressively Promote Opana After Becoming Aware of Its Widespread Abuse

686. The New York Attorney General found that Endo knew, as early as 2011, that Opana ER was being abused in New York, but certain sales representatives who detailed New York health care providers testified that they did not know about any policy or duty to report problematic conduct. The New York Attorney General further determined that Endo detailed health care providers who were subsequently arrested or convicted for illegal prescribing of opioids a total of 326 times, and these prescribers collectively wrote 1,370 prescriptions for Opana ER (although the subsequent criminal charges at issue did not involve Opana ER).

b. Repeated Admonishments and Fines Did Not Stop the Distributor Defendants from Ignoring Their Obligations to Control the Supply Chain and Prevent Diversion

687. Defendants were repeatedly admonished and even fined by regulatory authorities, but continued to disregard their obligations to control the supply chain of dangerous opioids and to institute controls to prevent diversion.

688. In a *60 Minutes* interview last fall, former DEA agent Joe Rannazzisi described Defendants' industry as "out of control," stating that "[w]hat they wanna do, is do what they wanna do, and not worry about what the law is. And if they don't follow the law in drug supply, people

die. That's just it. People die." The interview continued:

> JOE RANNAZZISI: The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.
>
> [INTERVIEWER]: You know the implication of what you're saying, that these big companies knew that they were pumping drugs into American communities that were killing people.
>
> JOE RANNAZZISI: That's not an implication, that's a fact. That's exactly what they did.

689. Another DEA veteran similarly stated that these companies failed to make even a "good faith effort" to "do the right thing." He explained that "I can tell you with 100 percent accuracy that we were in there on multiple occasions trying to get them to change their behavior. And they just flat out ignored us."[312]

690. Government actions against the Distributor Defendants with respect to their obligations to control the supply chain and prevent diversion include:

a. On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

[312] *Id.*

b. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

c. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an Order to Show Cause against the Cardinal Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On September 30, 2008, Cardinal entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn, Lakeland, Swedesboro and Stafford Facilities. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

g. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal's Lakeland Facility for failure to maintain effective controls against diversion of oxycodone; and

h. On December 23, 2016, Cardinal agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland Facility.

P. Joint Enterprise Allegations

691. Defendants entered into an agreement with respect to the unlawful marketing of opioids and/or distribution of opioids in Kentucky and Plaintiffs' communities.

692. The agreement had a common purpose: To promote the sale and distribution of opioids through the marketing of opioids and/or distribution of opioids into Kentucky and Plaintiffs' communities, in violation of the common law of fraud and nuisance.

693. The Defendants had a community of pecuniary interest in that common purpose, as all of the Defendants profited from sales of opioids in Kentucky and elsewhere.

694. The Defendants had an equal right to a voice in the direction of the enterprise.

VI. CLAIMS FOR RELIEF

COUNT I: RICO Violations (18 U.S.C. 1961, *et seq.*)
(Against all Defendants)

695. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege as follows.

696. Plaintiffs bring this Count on behalf of themselves against all Defendants.

697. The Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in-fact enterprise and/or a legal entity enterprise. At all relevant times, the Defendants were "persons" under 18 U.S.C.

§ 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

698. Section 1962(c) of RICO makes it unlawful "for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt." 18 U.S.C. § 1962(c); *United State v. Turkette*, 452 U.S. 576, 580 (1981).

699. The term "enterprise" is defined under federal law as including "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4); *Turkette*, 452 U.S. at 580; *Boyle v. U.S.*, 556 U.S. 938, 944 (2009). The definition of "enterprise" in Section 1961(4) includes legitimate and illegitimate enterprises within its scope. Specifically, the section "describes two separate categories of associations that come within the purview of an 'enterprise'—the first encompassing organizations such as corporations, partnerships, and other 'legal entities,' and the second covering 'any union or group of individuals associated in fact although not a legal entity.'" *Turkette*, 452 U.S. at 577. The second category is not a more generalized description of the first. *Id*.

700. For over a decade, Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, the Defendants are not permitted to engage in a limitless expansion of their market through the unlawful sales of regulated painkillers. As "registrants," the Defendants operated and continue to operate within the "closed-system" created under the Controlled Substances Act, 21 U.S.C. § 821, *et seq*. (the "CSA"). The CSA restricts the

Defendants' ability to manufacture or distribute Schedule II substances like opioids by requiring them to: (1) register to manufacture or distribute opioids; (2) maintain effective controls against diversion of the controlled substances that they manufacturer or distribute; (3) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA; and (4) make sales within a limited quota set by the DEA for the overall production of Schedule II substances like opioids.

701. The closed-system created by the CSA, including the establishment of quotas, was specifically intended to reduce or eliminate the diversion of Schedule II substances like opioids from "legitimate channels of trade to the illicit market by controlling the quantities of the basic ingredients needed for the manufacture of [controlled substances]."[313]

702. Finding it impossible to legally achieve their ever increasing sales ambitions, members of the Opioid Diversion Enterprise (as defined below) systematically and fraudulently violated their statutory duty to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders.[314] As discussed in detail below, through the Defendants' scheme, members of the Opioid Diversion Enterprise repeatedly engaged in unlawful sales of painkillers which, in turn, artificially and illegally increased the annual production quotas for opioids allowed by the DEA.[315] In doing so, the Defendants allowed hundreds of millions of pills to enter the illicit market which allowed them to generate large profits.

[313] 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).
[314] 21 U.S.C. § 823(a)(1), (b)(1); 21 C.F.R. § 1301.74(b)-(c).
[315] 21 C.F.R. § 1303.11(b); 21 C.F.R. § 1303.23.

703. Defendants' illegal scheme was hatched by an association-in-fact enterprise between the Marketing Defendants and the Distributor Defendants, and executed in perfect harmony by each of them. In particular, each of the Defendants were associated with, and conducted or participated in, the affairs of the enterprise (defined below and referred to collectively as the "Opioid Diversion Enterprise"), whose purpose was to engage in the unlawful sales of opioids and deceive the public and federal and state regulators into believing that the Defendants were faithfully fulfilling their statutory obligations. The Defendants' scheme allowed them to make billions in unlawful sales of opioids and, in turn, increase and/or maintain high production quotas with the purpose of ensuring unlawfully increasing revenues, profits, and market share. As a direct result of the Defendants' fraudulent scheme, course of conduct, and pattern of racketeering activity, they were able to extract billions of dollars of revenue from the addicted American public, while entities like the Plaintiffs experienced tens of millions of dollars of injury caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic. As explained in detail below, the Defendants' misconduct violated Section 1962(c), and Plaintiffs are entitled to treble damages for their injuries and damages under 18 U.S.C. § 1964(c).

704. Alternatively, the Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which the Defendants conducted their pattern of racketeering activity in Kentucky and throughout the United States. Specifically, the Healthcare Distribution Alliance (the "HDA")[316] is a distinct legal entity that satisfies the definition of a RICO enterprise. The HDA is a non-profit corporation formed under the laws of the District of Columbia

[316] Health Distribution Alliance, History (last accessed on September 15, 2017), https://www.healthcaredistribution.org/about/hda-history.

and doing business in Virginia. As a non-profit corporation, HDA qualifies as an "enterprise" within the definition set out in 18 U.S.C. § 1961(4) because it is a corporation and a legal entity.

705. On information and belief, each of the Defendants is a member, participant, and/or sponsor of the HDA and utilized the HDA to conduct the Opioid Diversion Enterprise and to engage in the pattern of racketeering activity that gives rise to the Count.

706. Each of the Defendants is a legal entity separate and distinct from the HDA. And the HDA serves the interests of distributors and manufacturers beyond the Defendants. Therefore, the HDA exists separately from the Opioid Diversion Enterprise, and each of the Defendants exists separately from the HDA. Therefore, the HDA may serve as a RICO enterprise.

707. The legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs were each used by the Defendants to conduct the Opioid Diversion Enterprise by engaging in a pattern of racketeering activity. Therefore, the legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs are pleaded in the alternative and are collectively referred to as the "Opioid Diversion Enterprise."

1. <u>The Opioid Diversion Enterprise</u>

708. Recognizing that there was a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the Controlled Substances Act in 1970.[317] The CSA and its implementing regulations created a closed-system of distribution for all controlled substances and listed chemicals.[318] Congress specifically designed the closed chain of distribution to prevent the diversion of legally

[317] Joseph T. Rannazzisi Decl. ¶ 4, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General*, D.D.C. Case No. 12- cv-185 (Document 14-2 February 10, 2012).
[318] *See* H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566.

produced controlled substances into the illicit market.[319] As reflected in comments from United States Senators during deliberation on the CSA, the "[CSA] is designed to crack down hard on the narcotics pusher and the illegal diverters of pep pills and goof balls."[320] Congress was concerned with the diversion of drugs out of legitimate channels of distribution when it enacted the CSA and acted to halt the "widespread diversion of [controlled substances] out of legitimate channels into the illegal market."[321] Moreover, the closed-system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain.[322] All registrants—manufacturers and distributors alike—must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion.[323] When registrants at any level fail to fulfill their obligations, the necessary checks and balances collapse.[324] The result is the scourge of addiction that has occurred.

709. In 2006 and 2007, the DEA issued multiple letters to the Distributor Defendants reminding them of their obligation to maintain effective controls against diversion of particular controlled substances, design and operate a system to disclose suspicious orders, and to inform the

[319] *Gonzalez v. Raich*, 545 U.S. 1, 12-14 (2005); 21 U.S.C. § 801(20; 21 U.S.C. §§ 821-824, 827, 880; H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970).
[320] *See* H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566; 116 Cong. Rec. 977-78 (Comments of Sen. Dodd, Jan 23, 1970).
[321] See Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United State Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).
[322] See Statement of Joseph T. Rannazzisi before the Caucus on International Narcotics Control United States Senate, July 18, 2012 (available at https://www.justice.gov/sites/default/files/testimonies/witnesses/attachments/07/18/12/07- 18-12-dea-rannazzisi.pdf).
[323] *Id.*
[324] Joseph T. Rannazzisi Decl. ¶ 10, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General*, D.D.C. Case No. 12-cv-185 (Document 14-2 February 10, 2012).

DEA of any suspicious orders.[325] The DEA also published suggested questions that a distributor should ask prior to shipping controlled substances, in order to "know their customers."[326]

710. Central to the closed-system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from "legitimate channels of trade" by controlling the "quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs."[327] When evaluating production quotas, the DEA was instructed to consider the following information:

(a) information provided by the Department of Health and Human Services;

(b) total net disposal of the basic class by all manufacturers;

(c) trends in the national rate of disposal of the basic class;

(d) an applicant's production cycle and current inventory position;

(e) total actual or estimated inventories of the class and of all substances manufactured from the class and trends in inventory accumulation; and

711. Other factors such as: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw materials; yield and

[325] Joseph T. Rannazzisi, In Reference to Registration # RC0183080 (September 27, 2006); Joseph T. Rannazzisi, In Reference to Registration # RC0183080 (December 27, 2007).
[326] Suggested Questions a Distributor should ask prior to shipping controlled substances, Drug Enforcement Administration (available at https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf).
[327] 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

sustainability issues; potential disruptions to production; and unforeseen emergencies.[328]

712. It is unlawful for a registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA, or (2) in excess of a quota assigned to it by the DEA.[329]

713. At all relevant times, the Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by disregarding their statutory duty to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market, in order to unlawfully increase the quotas set by the DEA and allow them to collectively benefit from the unlawful formation of a greater pool of prescription opioids from which to profit. The Defendants conducted their pattern of racketeering activity in Kentucky and throughout the United States through this enterprise.

714. The opioid epidemic has its origins in the mid-1990s when, between 1997 and 2007, per capita purchase of methadone, hydrocodone, and oxycodone increased 13-fold, 4-fold, and 9-fold, respectively. By 2010, enough prescription opioids were sold in the United States to medicate every adult in the country with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.[330] On information and belief, the Opioid Diversion Enterprise has been ongoing for at least the last decade.[331]

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[328] *See* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United State Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

[329] *Id.* (citing 21 U.S.C. 842(b)).

[330] Keyes KM, Cerdá M, Brady JE, Havens JR, Galea S. Understanding the rural-urban differences in nonmedical prescription opioid use and abuse in the United States. Am J Public Health. 2014;104(2):e52-9.

[331] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo- chamber-shaped-policy-amid-drug-epidemic.

715. The Opioid Diversion Enterprise was and is a shockingly successful endeavor. It Opioid Diversion Enterprise has been conducting business uninterrupted since its genesis. But, it was not until recently that United States and State regulators finally began to unravel the extent of the enterprise and the toll that it exacted on the American public.

716. At all relevant times, the Opioid Diversion Enterprise: (a) had an existence separate and distinct from each RICO Defendant; (b) was separate and distinct from the pattern of racketeering in which the Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the Defendants; (d)characterized by interpersonal relationships among the Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. Turkette, 452 U.S. at 580; Boyle, 556 U.S. at 944 (2009). Each member of the Opioid Diversion Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid sales generated as a result of the Opioid Diversion Enterprise's disregard for their duty to prevent diversion of their drugs into the illicit market and then requesting the DEA increase production quotas, all so that the Defendants would have a larger pool of prescription opioids from which to profit.

717. The Opioid Diversion Enterprise also engaged in efforts to lobby against the DEA's authority to hold the Defendants liable for disregarding their duty to prevent diversion. Members of the Pain Care Forum (described in greater detail below) and the Healthcare Distribution Alliance lobbied for the passage of legislation to weaken the DEA's enforcement authority. The Ensuring Patient Access and Effective Drug Enforcement Act significantly reduced the DEA's ability to

issue orders to show cause and to suspend and/or revoke registrations.[332] The HDA and other members of the Pain Care Forum contributed substantial amounts of money to political campaigns for federal candidates, state candidates, political action committees and political parties. Plaintiffs are informed and believe that the HDA devoted over a million dollars a year to its lobbying efforts between 2011 and 2016.

718. The Opioid Diversion Enterprise functioned by selling prescription opioids. While there are some legitimate uses and/or needs for prescription opioids, the Defendants, through their illegal enterprise, engaged in a pattern of racketeering activity, that involves a fraudulent scheme to increase revenue by violating State and Federal laws requiring the maintenance of effective controls against diversion of prescription opioids, and the identification, investigation, and reporting of suspicious orders of prescription opioids destined for the illicit drug market. The goal of Defendants' scheme was to increase profits from opioid sales. But, Defendants' profits were limited by the production quotas set by the DEA, so the Defendants refused to identify, investigate, and/or report suspicious orders of their prescription opioids being diverted into the illicit drug market. The end result of this strategy was to increase and maintain artificially high production

[332] *See* HDMA is now the Healthcare Distribution Alliance, Pharmaceutical Commerce, (June 13, 2016, updated July 6,2016), http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare- distribution- alliance/; Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea- slowed-enforcement-while-the-opioid-epidemic- grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13- d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls- for-investigation-of-dea-enforcement- slowdown/2017/03/06/5846ee60-028b-11e7-b1e9- a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent- we-had-no-leadership-in-wv-amid-flood-of-pain-pills-.

quotas of opioids so that there was a larger pool of opioids for Defendants to manufacture and distribute for public consumption.

719. The Opioid Diversion Enterprise engaged in, and its activities affected, interstate and foreign commerce because the enterprise involved commercial activities across states lines, such as manufacture, sale, distribution, and shipment of prescription opioids throughout the Kentucky, and the corresponding payment and/or receipt of money from the sale of the same.

720. Within the Opioid Diversion Enterprise, there were interpersonal relationships and common communication by which the Defendants shared information on a regular basis. These interpersonal relationships also formed the organization of the Opioid Diversion Enterprise. The Opioid Diversion Enterprise used their interpersonal relationships and communication network for the purpose of conducting the enterprise through a pattern of racketeering activity.

721. Each of the Defendants had a systematic link to each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities. The Defendants participated in the operation and management of the Opioid Diversion Enterprise by directing its affairs, as described herein. While the Defendants participated in, and are members of, the enterprise, they each have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

722. The Defendants exerted substantial control over the Opioid Diversion Enterprise by their membership in the Pain Care Forum, the HDA, and through their contractual relationships.

723. The Pain Care Forum ("PCF") has been described as a coalition of drugmakers, trade groups and dozens of non-profit organizations supported by industry funding. The PCF

recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

724. The Center for Public Integrity and The Associated Press obtained "internal documents shed [ding] new light on how drugmakers and their allies shaped the national response to the ongoing wave of prescription opioid abuse."167 [333] Specifically, PCF members spent over $740 million lobbying in the nation's capital and in all 50 statehouses on an array of issues, including opioid-related measures.[334]

725. Not surprisingly, each of the Defendants who stood to profit from lobbying in favor of prescription opioid use is a member of and/or participant in the PCF.[335] In 2012, membership and participating organizations included the HDA (of which all Defendants are members), Endo, Purdue, Johnson & Johnson (the parent company for Janssen Pharmaceuticals), Actavis (i.e., Allergan), and Teva (the parent company of Cephalon).[336] Each of the Marketing Defendants worked together through the PCF to advance the interests of the enterprise. But, the Marketing Defendants were not alone. The Distributor Defendants actively participated, and continue to

[333] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo- chamber-shaped-policy-amid-drug-epidemic (emphasis added).
[334] *Id.*
[335] PAIN CARE FORUM 2012 Meetings Schedule, (last updated December 2011), https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf
[336] *Id*. Plaintiff is informed and believes that Mallinckrodt became an active member of the PCF sometime after 2012.

participate in the PCF, at a minimum, through their trade organization, the HDA.[337] Plaintiffs are informed and believes that the Distributor Defendants participated directly in the PCF as well.

726. The 2012 Meeting Schedule for the Pain Care Forum is particularly revealing on the subject of the Defendants' interpersonal relationships. The meeting schedule indicates that meetings were held in the D.C. office of Powers Pyles Sutter & Verville on a monthly basis, unless otherwise noted. Local members were "encouraged to attend in person" at the monthly meetings. And, the meeting schedule indicates that the quarterly and year-end meetings included a "Guest Speaker."

727. The 2012 Pain Care Forum Meeting Schedule demonstrates that each of the Defendants participated in meetings on a monthly basis, either directly or through their trade organization, in a coalition of drugmakers and their allies whose sole purpose was to shape the national response to the ongoing prescription opioid epidemic, including the concerted lobbying efforts that the PCF undertook on behalf of its members.

728. Second, the HDA—or Healthcare Distribution Alliance—led to the formation of interpersonal relationships and an organization between the Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Marketing Defendants named in the Complaint, including Actavis (i.e., Allergan), Endo, Purdue, Mallinckrodt and Cephalon were members of the HDA.[338] And, the HDA

[337] *Id*. The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc., the Group President, Pharmaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation, and the President, U.S. Pharmaceutical for McKesson Corporation. Executive Committee, Healthcare Distribution Alliance (accessed on September 14, 2017), https://www.healthcaredistribution.org/about/executive-committee.

[338] Manufacturer Membership, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/about/membership/manufacturer.

and each of the Distributor Defendants, eagerly sought the active membership and participation of the Marketing Defendants by advocating that one of the benefits of membership included the ability to develop direct relationships between Manufacturers and Distributors at high executive levels.

729. In fact, the HDA touted the benefits of membership to the Marketing Defendants, advocating that membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "networking with HDA wholesale distributor members," "opportunities to host and sponsor HDA Board of Directors events," "participate on HDA committees, task forces and working groups with peers and trading partners," and "make connections."[339] Clearly, the HDA and the Distributor Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships between the Manufacturers and Defendants.

730. The application for manufacturer membership in the HDA further indicates the level of connection that existed between the Defendants.[340] The manufacturer membership application must be signed by a "senior company executive," and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company. The HDA application also requests that the manufacturer identify its current distribution information and its most recent year end net sales through any HDA distributors, including but not limited to, Defendants AmerisourceBergen, Cardinal Health, and McKesson.[341]

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339 Manufacturer Membership Benefits, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/~/media/pdfs/membership/manufacturer-membership-benefits.ashx?la=en.

340 Manufacturer Membership Application, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/~/media/pdfs/membership/manufacturer-membership- application.ashx?la=en.

341 *Id.*

731. After becoming members, the Distributors and Manufacturers were eligible to participate on councils, committees, task forces, and working groups, including:

a. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues;"[342]

b. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce." Participation in this committee includes distributors and manufacturer members;[343]

c. Health, Beauty and Wellness Committee: "This committee conducts research, as well as creates and exchanges industry knowledge to help shape the future of the distribution for health, beauty and wellness/consumer products in the healthcare supply chain." Participation in this committee includes distributors and manufacturer members;[344]

d. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality

[342] Councils and Committees, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/about/councils-and-committees
[343] *Id.*
[344] *Id.*

improvement." Participation in this committee includes distributors and manufacturer members;[345]

e. Manufacturer Government Affairs Advisory Committee: "This committee provides a forum for briefing HDA's manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement." Participation in this committee includes manufacturer members;[346]

f. Bar Code Task Force: Participation includes Distributor, Manufacturer and Service Provider Members;[347]

g. eCommerce Task Force: Participation includes Distributor, Manufacturer and Service Provider Members;[348]and

h. ASN Working Group: Participation includes Distributor, Manufacturer and Service Provider Members;[349]

i. Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry

[345] *Id.*
[346] *Id.*
[347] *Id.*
[348] *Id.*
[349] *Id.*

knowledge of interest to contract and chargeback professionals." Participation includes Distributor and Manufacturer Members.[350]

732. The councils, committees, task forces, and working groups provided the Manufacturer and Distributor Defendants with the opportunity to work closely together in shaping their common goals and forming the enterprise's organization.

733. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences to the Marketing Defendants as an opportunity to "bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues."[351] The conferences also gave the Manufacturer and Distributor Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry."[352]The HDA and its conferences were significant opportunities for the Manufacturer and Distributor Defendants to interact at a high-level of leadership. And, it is clear that the Marketing Defendants embraced this opportunity by attending and sponsoring these events.[353]

734. Third, the Defendants maintained their interpersonal relationships by working together and exchanging information and driving the unlawful sales of their opioids through their contractual relationships, including chargebacks and vault security programs.

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[350] *Id.*

[351] Business and Leadership Conference – Information for Manufacturers, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/events/2015-business-and-leadership- conference/blc-for-manufacturers.

[352] *Id.*

[353] 2015 Distribution Management Conference and Expo, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/events/2015-distribution-management-conference.

735. The Marketing Defendants engaged in an industry-wide practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids.[354] As reported in the Washington Post, identified by Senator McCaskill, and acknowledged by the HDA, there is an industry-wide practice whereby the Manufacturers paid the Distributors rebates and/or chargebacks on their prescription opioid sales.[355] On information and belief, these contracts were negotiated at the highest levels, demonstrating ongoing relationships between the Manufacturer and Distributor Defendants. In return for the rebates and chargebacks, the Distributor Defendants provided the Marketing Defendants with detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices.[356] The Marketing Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell the prescription opioids.

736. The contractual relationships among the Defendants also include vault security programs. The Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opiates. Plaintiffs are informed and believe that manufacturers negotiated agreements whereby the Manufacturers installed security vaults for Distributors in exchange for agreements to maintain minimum sales performance thresholds.

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[354] Lenny Bernstein & Scott Higham, The government's struggle to hold opioid manufacturers accountable, The Washington Post, (April 2, 2017), https://www.washingtonpost.com/ graphics/investigations/dea- mallinckrodt/?utm_term=.b24cc81cc356; *see also*, Letter from Sen. Claire McCaskill, (July 27, 2017), https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png; Letter from Sen. Claire McCaskill, (July 27, 2017), https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png; Letters From Sen. Claire McCaskill, (March 28, 2017), https://www.mccaskill.senate.gov/opioid-investigation; Purdue Managed Markets, Purdue Pharma, (accessed on September 14, 2017), http://www.purduepharma.com/payers/managed-markets/.

[355] *Id.*

[356] Webinars, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/resources/webinar-leveraging-edi.

Plaintiffs are informed and believe that these agreements were used by the Defendants as a tool to violate their reporting and diversion duties in order to reach the required sales requirements.

737. Taken together, the interaction and length of the relationships between and among the Manufacturer and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. The Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids. The HDA and the Pain Care Forum are but two examples of the overlapping relationships, and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the Defendants was in communication and cooperation.

738. According to articles published by the Center for Public Integrity and The Associated Press, the Pain Care Forum -- whose members include the Manufacturers and the Distributors' trade association has been lobbying on behalf of the Manufacturers and Distributors for "more than a decade."[357] And, from 2006 to 2016 the Distributors and Manufacturers worked together through the Pain Care Forum to spend over $740 million lobbying in the nation's capital and in all 50 statehouses on issues including opioid-related measures.[358] Similarly, the HDA has continued its work on behalf of Distributors and Manufacturers, without interruption, since at least 2000, if not longer.[359]

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[357] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic.

[358] *Id.*

[359] HDA History, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/about/hda-history.

739. As described above, the Defendants began working together as early as 2006 through the Pain Care Forum and/or the HDA to promote the common purpose of their enterprise. Plaintiffs are informed and believes that the Defendants worked together as an ongoing and continuous organization throughout the existence of their enterprise.

2. Conduct of the Opioid Diversion Enterprise

740. During the time period alleged in this Complaint, the Defendants exerted control over, conducted and/or participated in the Opioid Diversion Enterprise by fraudulently failing to comply with their Federal and State obligations to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, to halt such unlawful sales and, in doing so, to increase production quotas and generate unlawful profits, as follows:

741. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to maintain effective controls against diversion of their prescription opioids.

742. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids.

743. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids.

744. Defendants paid nearly $800 million dollars to influence local, state, and federal governments through joint lobbying efforts as part of the Pain Care Forum. The Defendants were all members of their Pain Care Forum either directly or indirectly through the HDA. The lobbying

efforts of the Pain Care Forum and its members, included efforts to pass legislation making it more difficult for the DEA to suspend and/or revoke the Manufacturers' and Distributors' registrations for failure to report suspicious orders of opioids.

745. The Defendants exercised control and influence over the distribution industry by participating and maintaining membership in the HDA.

746. The Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."[360]

747. The Defendants engaged in an industry-wide practice of paying rebates and chargebacks to incentivize unlawful opioid prescription sales. Plaintiffs are informed and believes that the Marketing Defendants used the chargeback program to acquire detailed high-level data regarding sales of the opioids they manufactured. And, Plaintiffs are informed and believes that the Marketing Defendants used this high-level information to direct the Distributor Defendants' sales efforts to regions where prescription opioids were selling in larger volumes.

748. The Marketing Defendants lobbied the DEA to increase Aggregate Production

[360] *See* HDMA is now the Healthcare Distribution Alliance, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/; Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea- slowed- enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement- slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-.

Quotas, year after year by submitting net disposal information that the Marketing Defendants knew included sales that were suspicious and involved the diversion of opioids that had not been properly investigated or reported by the Defendants. The Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007 was intended to help the Defendants identify suspicious orders or customers who were likely to divert prescription opioids.[361] On information and belief, the "know your customer" questionnaires informed the Defendants of the number of pills that the pharmacies sold, how many non-controlled substances are sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

749. The Defendants refused to identify, investigate, and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings. The Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012[362] and 117 recommended decision in registrant actions from The Office of Administrative Law Judges. These numbers include 76 actions involving orders to show cause and 41 actions

[361] Suggested Questions a Distributor should ask prior to shipping controlled substances, Drug Enforcement Administration (available at https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf); Richard Widup, Jr., Kathleen H. Dooley, Esq. Pharmaceutical Production Diversion: Beyond the PDMA, Purdue Pharma and McQuite Woods LLC,(available at https://www.mcguirewoods.com/news- resources/publications/lifesciences/product_diversion_beyond_pdma.pdf).

[362] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.

involving immediate suspension orders—all for failure to report suspicious orders.[363]

750. Defendants' scheme had decision-making structure that was driven by the Marketing Defendants and corroborated by the Distributor Defendants. The Marketing Defendants worked together to control the government's response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion, and identify suspicious orders and report them to the DEA.

751. The Defendants worked together to control the flow of information and influence state and federal governments and political candidates to pass legislation that was pro- opioid. The Manufacturer and Distributor Defendants did this through their participation in the Pain Care Forum and Healthcare Distributors Alliance.

752. The Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA stayed high and ensured that suspicious orders were not reported to the DEA. By not reporting suspicious orders or diversion of prescription opioids, the Defendants ensured that the DEA had no basis for refusing to increase or decrease the production quotas for prescription opioids due to diversion of suspicious orders. The Defendants influenced the DEA production quotas in the following ways:

a. the Distributor Defendants assisted the enterprise and the Marketing Defendants in their lobbying efforts through the Pain Care Forum;

b. the Distributor Defendants invited the participation, oversight and control of the Marketing Defendants by including them in the HDA, including on the councils, committees, task forces, and working groups;

[363] *Id.*

c. the Distributor Defendants provided sales information to the Marketing Defendants regarding their prescription opioids, including reports of all opioids prescriptions filled by the Distributor Defendants;

d. the Manufacturer Defendants used a chargeback program to ensure delivery of the Distributor Defendants' sales information;

e. the Marketing Defendants obtained sales information from QuintilesIMS (formerly IMS Health) that gave them a "stream of data showing how individual doctors across the nation were prescribing opioids";[364]

f. the Distributor Defendants accepted rebates and chargebacks for orders of prescription opioids;

g. the Marketing Defendants used the Distributor Defendants' sales information and the data from QuintilesIMS to instruct the Distributor Defendants to focus their distribution efforts to specific areas where the purchase of prescription opioids was most frequent;

h. the Defendants identified suspicious orders of prescription opioids and then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market;

i. the Defendants refused to report suspicious orders of prescription opioids despite repeated investigation and punishment of the Distributor Defendants by the DEA for failure to report suspicious orders; and

[364] Harriet Ryan, et al., *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew*, Los Angeles Times, (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/.

j. the Defendants withheld information regarding suspicious orders and illicit diversion from the DEA because it would have revealed that the "medical need" for and the net disposal of their drugs did not justify the production quotas set by the DEA.

753. The scheme devised and implemented by the Defendants amounted to a common course of conduct characterized by a refusal to maintain effective controls against diversion, and all designed and operated to ensure the continued unlawful sale of controlled substances.

3. Pattern of Racketeering Activity

754. The Defendants conducted and participated in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(B), including mail fraud (18 U.S.C. § 1341) and wire fraud (18 U.S.C. § 1343), and 18 U.S.C. § 1961(D), by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

755. The Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators, and the American public by knowingly conducting or participating in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

756. The Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the Defendants committed, or aided and abetted in the commission of, were related to each other,

posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Diversion Enterprise. The Defendants participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in interstate or foreign commerce.

757. The Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

758. In devising and executing the illegal scheme, the Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts. For the purpose of executing the illegal scheme, the Defendants committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

759. The Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

a. Mail Fraud: The Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions; and

b. Wire Fraud: The Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

c. The Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Manufacturers, Distributors, or third parties that were foreseeably caused to be sent as a result of the Defendants' illegal scheme, including but not limited to:

d. the prescription opioids themselves;

e. documents and communications that facilitated the manufacture, purchase and unlawful sale of prescription opioids;

f. Defendants' DEA registrations;

g. documents and communications that supported and/or facilitated Defendants' DEA registrations;

h. documents and communications that supported and/or facilitated the Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;

i. Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;

j. documents and communications related to the Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;

k. documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;

l. documents for processing and receiving payment for prescription opioids;

m. payments from the Distributors to the Manufacturers;

n. rebates and chargebacks from the Manufacturers to the Distributors;

o. payments to Defendants' lobbyists through the Pain Care Forum;

p. payments to Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;

q. deposits of proceeds from Defendants' manufacture and distribution of prescription opioids; and

r. other documents and things, including electronic communications.

760. On information and belief, the Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

761. Purdue manufactures multiple forms of prescription opioids, including but not limited to: OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER. Purdue manufactured and shipped these prescription opioids to the Distributor Defendants in Kentucky.

762. The Distributor Defendants shipped Purdue's prescription opioids throughout Kentucky.

763. Cephalon manufactures multiple forms of prescription opioids, including but not

limited to: Actiq and Fentora. Cephalon manufactured and shipped these prescription opioids to the Distributor Defendants in Kentucky.

764. The Distributor Defendants shipped Teva's prescription opioids throughout Kentucky.

765. Janssen manufactures prescription opioids known as Duragesic. Janssen manufactured and shipped its prescription opioids to the Distributor Defendants in Kentucky.

766. The Distributor Defendants shipped Janssen's prescription opioids throughout Kentucky.

767. Endo manufactures multiple forms of prescription opioids, including but not limited to: Opana/Opana ER, Percodan, Percocet, and Zydone. Endo manufactured and shipped its prescription opioids to the Distributor Defendants in Kentucky.

768. The Distributor Defendants shipped Janssen's prescription opioids throughout Kentucky.

769. Actavis manufactures multiple forms of prescription opioids, including but not limited to: Kadin and Norco, as well as generic versions of the drugs known as Kadian, Duragesic and Opana. Actavis manufactured and shipped its prescription opioids to the Distributor Defendants in Kentucky.

770. The Distributor Defendants shipped Actavis' prescription opioids throughout Kentucky.

771. Mallinckrodt manufactures multiple forms of prescription opioids, including but not limited to: Exalgo and Roxicodone.

772. The Distributor Defendants shipped Mallinckrodt's prescription opioids throughout Kentucky.

773. The Defendants also used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

774. At the same time, the Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids and that they complied with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

775. Plaintiffs are also informed and believe that the Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

776. The Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

777. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct to deceive regulators and the public that Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The Defendants' scheme and common course of conduct was intended to increase or maintain high production quotas for their prescription opioids from which they could profit.

778. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire

facilities have been deliberately hidden, and cannot be alleged without access to Defendants' books and records. But, Plaintiffs have described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

779. The Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. These actions violate 18 U.S.C. § 1962(c). Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with the Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the Defendants.

780. The Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

781. The Defendants hid from the general public, and suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities, about the reality of the suspicious orders that the Defendants were filling on a daily basis – leading to the diversion of a tens of millions of doses of prescriptions opioids into the illicit market.

782. The Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

783. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding marketing prescription opioids and refusing to report suspicious orders.

784. As described herein, the Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

785. The predicate acts all had the purpose of generating significant revenue and profits for the Defendants while Plaintiffs was left with substantial injury to its business through the damage that the prescription opioid epidemic caused. The predicate acts were committed or caused to be committed by the Defendants through their participation in the Opioid Diversion Enterprise and in furtherance of its fraudulent scheme.

786. The pattern of racketeering activity alleged herein and the Opioid Diversion Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the enterprise.

787. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

788. Many of the precise dates of the Defendants' criminal actions at issue here have been hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioids Addiction and Opioid Diversion Enterprise alleged herein depended upon secrecy.

789. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar

results affecting similar victims, including consumers in Kentucky and the Plaintiffs. Defendants calculated and intentionally crafted the Opioid Diversion Enterprise and their scheme to increase and maintain their increased profits, without regard to the effect such behavior would have on consumers in Kentucky, its citizens, or the Plaintiffs. In designing and implementing the scheme, at all times Defendants were cognizant of the fact that those in the manufacturing and distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and reliable information regarding Defendants' products and their manufacture and distribution of those products. The Defendants were also aware that Plaintiffs and Plaintiffs' communities rely on the Defendants to maintain a closed system and to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

790. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

791. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations, would harm Plaintiffs by allowing the flow of prescriptions opioids from appropriate medical channels into the illicit drug market.

792. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

793. The Defendants conducted and participated in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(D) by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

794. The Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 483(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter. A violation of section 483(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 483(d)(1).

795. Each of the Defendants qualify as registrants under the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances, and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

796. Pursuant to the CSA and the Code of Federal Regulations, the Defendants were required to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders.

797. The Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other document required to be filed with the DEA including the Marketing Defendants' applications for production quotas. Specifically, the Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

798. For example, the DEA and DOJ began investigating McKesson in 2013 regarding its monitoring and reporting of suspicious controlled substances orders. On April 23, 2015,

McKesson filed a Form-8-K announcing a settlement with the DEA and DOJ wherein it admitted to violating the CSA and agreed to pay $150 million and have some of its DEA registrations suspended on a staggered basis. The settlement was finalized on January 17, 2017.[365]

799. Purdue's experience in Los Angeles is another striking example of Defendants' willful violation of the CSA and Code of Federal Regulations as it relates to reporting suspicious orders of prescription opioids. In 2016, the Los Angeles Times reported that Purdue was aware of a pill mill operating out of Los Angeles yet failed to alert the DEA.[366] The LA Times uncovered that Purdue began tracking a surge in prescriptions in Los Angeles, including one prescriber in particular. A Purdue sales manager spoke with company officials in 2009 about the prescriber, asking "Shouldn't the DEA be contacted about this?" and adding that she felt "very certain this is an organized drug ring."[367]Despite knowledge of the staggering amount of pills being issued in Los Angeles, and internal discussion of the problem, "Purdue did not shut off the supply of highly addictive OxyContin and did not tell authorities what it knew about Lake Medical until several years later when the clinic was out of business and its leaders indicted. By that time, 1.1 million pills had spilled into the hands of Armenian mobsters, the Crips gang and other criminals."[368]

800. Finally, Mallinckrodt was recently the subject of a DEA and Senate investigation for its opioid practices. Specifically, in 2011, the DEA targeted Mallinckrodt arguing that it ignored its responsibility to report suspicious orders as 500 million of its pills ended up in Florida

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[365] McKesson, McKesson Finalizes Settlement with U.S. Department of Justice and U.S. Drug Enforcement Administration to Resolve Past Claims, About McKesson / Newsroom / Press Releases, (January 17, 2017), http://www.mckesson.com/about-mckesson/newsroom/press-releases/2017/mckesson-finalizes-settlement-with-doj- and-dea-to-resolve-past-claims/.
[366] Harriet Ryan, et al., More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew, Los Angeles Times, (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/.
[367] *Id.*
[368] *Id.*

between 2008 and 2012.[369] After six years of DEA investigation, Mallinckrodt agreed to a settlement involving a $35 million fine. Federal prosecutors summarized the case by saying that Mallinckrodt's response was that everyone knew what was going on in Florida but they had no duty to report it.[370]

801. Plaintiff is informed and believes that the foregoing examples reflect the Defendants' pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74. This conclusion is supported by the sheer volume of enforcement actions available in the public record against the Distributor Defendants.[371] For example:

802. On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration; On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone; On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland

[369] Lenny Bernstein & Scott Higham, The government's struggle to hold opioid manufacturers accountable, The Washington Post, (April 2, 2017), https://www.washingtonpost.com/ graphics/investigations/dea- mallinckrodt/?utm_term=.b24cc81cc356. This number accounted for 66% of all oxycodone sold in the state of Florida during that time.
[370] *Id.*
[371] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.

Facility") for failure to maintain effective controls against diversion of hydrocodone;

803. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone; On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone; On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program"; On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

804. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone; On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and

On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a $150,000,000 civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and West Sacramento CA. These actions against the Distributor Defendants confirm that the Distributors knew they had a duty to maintain effective controls against diversion, design and operate a system to disclose suspicious orders, and to report suspicious orders to the DEA. These actions also demonstrate, on information and belief, that the Marketing Defendants were aware of the enforcement against their Distributors and the diversion of the prescription opioids and a corresponding duty to report suspicious orders.

805. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

806. Many of the precise dates of Defendants' criminal actions at issue herein were hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Diversion Enterprise depended upon the secrecy of the participants in that enterprise.

807. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers in Kentucky and the Plaintiffs. Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on Kentucky, its citizens, or the Plaintiffs. The Defendants were aware that Plaintiffs and Plaintiffs' communities

rely on the Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

808. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

809. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations would harm Plaintiff by allowing the flow of prescriptions opioids from appropriate medical channels.

810. The last racketeering incident occurred within four years of the commission of a prior incident of racketeering.

4. Damages

811. The Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiffs injury in their businesses and property because Plaintiffs paid increased costs associated with the opioid epidemic, as described above in language expressly incorporated herein by reference.

812. Plaintiffs' injuries were proximately caused by Defendants' racketeering activities. But for the Defendants' conduct, Plaintiffs would not have paid the health services and expenditures required as a result of the plague of drug-addicted residents.

813. Plaintiffs' injuries were directly caused by the Defendants' racketeering activities.

814. Plaintiffs seek all legal and equitable relief as allowed by law, including *inter alia* actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney's fees, all costs and expenses of suit, and pre- and post-judgment interest.

COUNT II: RICO Conspiracy (18 U.S.C. 1962(d))
(Against all Defendants)

815. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein.

816. Plaintiffs bring this claim against all Defendants. At all relevant times, the Defendants were associated with the Opioid Diversion Enterprise and agreed and conspired to violate 18 U.S.C. § 1962(c), that is, they agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity.

817. Defendants conspired, as alleged more fully above, by conducting the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity, as incorporated by reference below.

818. The Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiffs injuries in their businesses and property because Plaintiffs paid for costs associated with the opioid epidemic, as described above in language expressly incorporated herein by reference.

819. Plaintiffs' injuries were proximately caused by the Defendants' racketeering activities. But for the Defendants' conduct, Plaintiffs would not have paid the health services and expenditures required as a result of the plague of drug-addicted residents.

820. Plaintiffs' injuries were directly caused by the Defendants' racketeering activities.

821. Plaintiffs seek all legal and equitable relief as allowed by law, including *inter alia* actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorneys' fees, and all costs and expenses of suit, and pre- and post-judgment interest.

COUNT III: Negligence
(Against all Defendants)

822. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein.

823. To establish actionable negligence, one must show in addition to the existence of a duty, a breach of that duty, and loss or damage caused by the breach, and actual loss or damage to another. All such essential elements exist here.

824. Kentucky law has adopted a "universal duty of care," which requires every person to exercise ordinary care in his activities to prevent foreseeable injury.

825. Each Defendant had a duty to exercise reasonable care in the manufacturing, marketing, selling, and distributing of highly dangerous opioid drugs.

826. Each Defendant breached its aforesaid duties by its conduct previously specified herein.

827. As a direct and proximate result of Defendants' conduct, Plaintiffs have suffered actual injury and damages including, but not limited to, significant increased expenses for providing public health services, including but not limited to: (1) providing vaccinations and public health services related to public outbreaks of HIV, Hepatitis A, B, and C; (2) administering and operating needle exchange programs; (3) providing public safety relating to the opioid epidemic; (4) providing public health educational programs on preventing opioid addiction, abuse, and/or dependency; (5) providing prenatal services to infants and mothers with opioid-related medical conditions; (6) providing services for at least the first two years of a child's life, to children born with opioid-related medical conditions and children whose families suffer from opioid-related disabilities or incapacitation; and (7) providing services for at least the first two years of a child's life, to mothers and families of

children suffering from opioid-related medical conditions.

828. Each Defendant owed its aforesaid duties to Plaintiffs because the injuries alleged herein were foreseeable by the Defendants.

829. The injuries to Plaintiffs would not have happened in the ordinary course of events had Defendants used due care commensurate to the dangers involved in the manufacture, marketing, sale and distribution of opioids.

830. Plaintiffs seeks compensatory damages for their monetary losses previously specified herein, plus interest and the costs of this action.

COUNT IV: Wanton Negligence
(Against all Defendants)

831. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein.

832. Defendants conducted themselves with reckless indifference to the consequences of their acts and omissions, in that they were conscious of their conduct and were aware, from their knowledge of existing circumstances and conditions, that their conduct would inevitably or probably result in injury to others, specifically health departments such as Plaintiffs, including, but not limited to, significant increased expenses for providing public health services, including but not limited to: (1) providing vaccinations and public health services related to public outbreaks of HIV, Hepatitis A, B, and C; (2) administering and operating needle exchange programs; (3) providing public safety relating to the opioid epidemic; (4) providing public health educational programs on preventing opioid addiction, abuse, and/or dependency; (5) providing prenatal services to infants and mothers with opioid-related medical conditions; (6) providing services for at least the first two years of a child's life, to children born with opioid-related medical conditions and children whose families suffer from opioid-related

disabilities or incapacitation; and (7) providing services for at least the first two years of a child's life, to mothers and families of children suffering from opioid-related medical conditions.

833. As a proximate result of Defendants' wanton negligence, Plaintiffs were monetarily damaged as aforesaid.

834. Plaintiffs seek compensatory and punitive damages, plus the costs of this action.

COUNT V: Negligence per se
(Against all Defendants)

835. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein.

836. Under Kentucky law, it has been declared that "[t]he regulation of controlled substances in this Commonwealth is important and necessary for the preservation of public safety and public health." KRS 218A.005(1).

837. Pursuant to Kentucky Board of Pharmacy law, "effective control and legislation" of "all persons who are required to obtain a license, certificate, or permit from the Board of Pharmacy, whether located in or outside the Commonwealth, that distribute, manufacture, or sell drugs within the Commonwealth" is necessary to "promote, preserve, and protect public health, safety, and welfare." KRS 315.005.

838. Pursuant to KRS 218A.200, manufacturers and wholesalers of opioids "shall keep records of all controlled substances compounded, mixed, cultivated, grown, or by any other process produced or prepared, and all of controlled substances received and disposed of by them."

839. Kentucky law requires that a "manufacturer, distributor, or wholesaler" must comply with "KRS 218A.200 and the federal controlled substances laws." KRS 218A.170.

840. Kentucky Board of Pharmacy licensure requirements mandate that a wholesale

distributor "continue[] to demonstrate acceptable operational procedures, including . . . compliance with all DEA regulations." 201 KAR 2:105 § 2(4)(d).

841. Defendants violated both State and Federal Controlled Substances act in failing to report suspicious orders of opioid pain medications in Kentucky. Defendants violated state law in failing to maintain effective controls against the diversion of opioids into other than legitimate medical channels. Defendants also violated state law in failing to operate a system to stop orders which is flagged or should have been flagged as suspicious.

842. Each Defendant's actions were in violation of Chapter 218A of the Kentucky Revised Statutes, as set out above, including but not limited to KRS 218A.1404(3), which forbids unlawful distribution of controlled substances; KRS 218A.1404(1), which forbids the trafficking of controlled substances; KRS 506.040 and 218A.1402, which forbid criminal drug conspiracies; and KRS 218A.1405, which forbids receipt of income from trafficking and utilizing that income to operate a commercial enterprise.

843. Failure to comply with the Kentucky law and the CSA constitutes negligence *per se.*

844. The CSA requires that the Defendants know their customers, which includes an awareness of the customer base, knowledge of the average prescriptions filled each day, the percentage of controlled substances compared to overall purchases, a description of how the dispenser fulfills its responsibility to ensure that prescriptions filled are for legitimate medical purposes, and identification of physicians and bogus centers for the alleged treatment of pain that are the dispenser's most frequent prescribers.

845. Defendants have failed to diligently respond to suspicious orders in contravention of Kentucky law.

846. Defendants have failed to provide effective controls and procedures to guard against diversion of controlled substances in contravention of Kentucky law.

847. Defendants have willfully turned a blind eye towards the actual facts by regularly distributing large quantities of controlled substances to retailers and dispensers who are serving a customer base substantially comprised of individuals who are abusing and/or diverting prescription medications, many of whom are addicted and all of whom can reasonably be expected to become addicted.

848. Defendants negligently acted with others by dispensing controlled substances for illegitimate medical purposes, operating bogus pain clinics which do little more than provide prescriptions for controlled substances, thereby creating and continuing addictions to prescription medications in this state.

849. Defendants have, by their acts and omissions, proximately caused and substantially contributed to damages to Plaintiffs by violating Kentucky law, by creating conditions which contribute to violations of Kentucky laws by others, and by their negligent and/or reckless disregard of the customs, standards, and practices within their own industry.

850. Plaintiffs have suffered and will continue to suffer enormous damages as the proximate result of the failure by Defendants to comply with Kentucky law.

851. Defendants' acts and omissions imposed an unreasonable risk of harm to others separately and/or combined with the negligent and/or criminal acts of third parties.

852. Plaintiffs are within the class of persons the CSA is intended to protect.

853. The harm that has occurred is the type of harm that the CSA is intended to guard against.

854. Defendants breached their duty by failing to take any action to prevent or reduce

the distribution of the opioids.

855. As a direct and proximate result of Defendants' negligence *per se*, Plaintiffs have suffered and continues to suffer injury, including, but not limited to, significant increased expenses for providing public health services, including but not limited to: (1) providing vaccinations and public health services related to public outbreaks of HIV, Hepatitis A, B, and C; (2) administering and operating needle exchange programs; (3) providing public safety relating to the opioid epidemic; (4) providing public health educational programs on preventing opioid addiction, abuse, and/or dependency; (5) providing prenatal services to infants and mothers with opioid-related medical conditions; (6) providing services for at least the first two years of a child's life, to children born with opioid-related medical conditions and children whose families suffer from opioid-related disabilities or incapacitation; and (7) providing services for at least the first two years of a child's life, to mothers and families of children suffering from opioid-related medical conditions.

856. Defendants were negligent in failing to monitor and guard against third-party misconduct and participated and enabled such misconduct.

857. Defendants were negligent in failing to monitor against diversion of opioid pain medications.

858. Defendants' violations constitute negligence *per se*.

859. Plaintiffs are entitled to recover damages caused by Defendants' in an amount to be determined at trial.

COUNT VI: Negligent Marketing
(Against the Marketing Defendants)

860. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein.

861. Defendants had a duty to exercise reasonable care in the marketing of opioids.

862. Defendants were aware of the dangerous nature of opioids.

863. Defendants marketed opioids in an improper manner by:

a. Overstating the benefits of chronic opioid therapy, promising improvement in patients' function and quality of life, and failing to disclose the lack of evidence supporting long-term use;

b. Trivializing or obscuring opioids' serious risks and adverse outcomes, including the risk of addiction, overdose and death;

c. Overstating opioids' superiority compared with other treatments, such as other non-opioid analgesics, physical therapy, and other alternatives;

d. Mischaracterizing the difficulty of withdrawal from opioids and the prevalence of withdrawal symptoms;

e. Marketing opioids for indications and benefits that were outside of the opioids' labels and not supported by substantial evidence.

864. It was Defendants' marketing – and not any medical breakthrough – that rationalized prescribing opioids for chronic pain and opened the floodgates of opioid use and abuse. The result has been catastrophic.

865. Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements indirectly, through KOLs and Front Groups, and in unbranded marketing materials. These KOLs and Front Groups were important elements of Defendants' marketing plans, which specifically contemplated their use, because they seemed independent and therefore outside FDA oversight. Through unbranded materials, Defendants, with their own knowledge of the risks, benefits and advantages of opioids, presented information and instructions concerning

opioids generally that were contrary to, or at best, inconsistent with information and instructions listed on Defendants' branded marketing materials and drug labels. Defendants did so knowing that unbranded materials typically are not submitted to or reviewed by the FDA.

866. Defendants also marketed opioids through the following vehicles: (a) KOLs, who could be counted upon to write favorable journal articles and deliver supportive CMEs; (b) a body of biased and unsupported scientific literature; (c) treatment guidelines; (d) CMEs; (e) unbranded patient education materials; and (f) Front Group patient-advocacy and professional organizations, which exercised their influence both directly and through Defendant-controlled KOLs who served in leadership roles in those organizations.

867. Defendants knew or should have known that opioids were unreasonably dangerous and could cause addiction.

868. Defendants have a duty to exercise reasonable care in the distribution, promotion and marketing or opioids.

869. Defendants breached their duty by failing to take any action to prevent or reduce the unlawful distribution of opioids.

870. Defendants' marketing was a factor for physicians, patients, and others to prescribe or purchase opioids.

871. As a direct and proximate result of Defendants' negligence, Plaintiffs have suffered and continue to suffer injury, including but not limited to significant increased expenses for providing public health services, including but not limited to: (1) providing vaccinations and public health services related to public outbreaks of HIV, Hepatitis A, B, and C; (2) administering and operating needle exchange programs; (3) providing public safety relating to the opioid epidemic; (4) providing public health educational programs on preventing opioid

addiction, abuse, and/or dependency; (5) providing prenatal services to infants and mothers with opioid-related medical conditions; (6) providing services for at least the first two years of a child's life, to children born with opioid-related medical conditions and children whose families suffer from opioid-related disabilities or incapacitation; and (7) providing services for at least the first two years of a child's life, to mothers and families of children suffering from opioid-related medical conditions.

872. Plaintiffs are entitled to recover damages caused by Defendants' negligence in an amount to be determined at trial.

COUNT VII: Negligent Distribution
(Against All Defendants)

873. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein.

874. Defendants had a duty not to breach the standard of care established under Kentucky law and the Controlled Substance Act ("CSA") and implementing regulations and to exercise reasonable care in the distribution of opioids.

875. Defendants were aware of the potentially dangerous situation involving opioids.

876. Defendants distributed opioids in an improper manner by:

a. Distributing and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;

b. Distributing and selling opioids without maintaining effective controls against diversion;

c. Choosing not to or failing to effectively monitor for suspicious orders;

d. Choosing not to or failing to report suspicious orders;

e. Choosing not to or failing to stop or suspend shipments of suspicious orders; and

f. Distributing and selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills."

877. Defendants' negligent breach of their duties resulted in foreseeable harm and injury to Plaintiffs.

878. As a direct and proximate result of Defendants' negligence, Plaintiffs suffered and will continue to suffer damages including, but not limited to, significant increased expenses for providing public health services, including but not limited to: (1) providing vaccinations and public health services related to public outbreaks of HIV, Hepatitis A, B, and C; (2) administering and operating needle exchange programs; (3) providing public safety relating to the opioid epidemic; (4) providing public health educational programs on preventing opioid addiction, abuse, and/or dependency; (5) providing prenatal services to infants and mothers with opioid-related medical conditions; (6) providing services for at least the first two years of a child's life, to children born with opioid-related medical conditions and children whose families suffer from opioid-related disabilities or incapacitation; and (7) providing services for at least the first two years of a child's life, to mothers and families of children suffering from opioid-related medical conditions.

879. Plaintiffs are entitled to recover damages caused by Defendants' negligence in an amount to be determined at trial.

COUNT VIII: Nuisance
(Against All Defendants)

880. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this

Complaint, as if fully set forth herein.

881. The nuisance is the over-saturation of opioids in the patient population of Plaintiffs and in the geographic areas served by Plaintiffs for illegitimate purposes, as well as the adverse social, economic, and human health outcomes associated with widespread illegal opioid use.

882. Defendants, individually and acting through their employees and agents, through fraudulent and deceptive marketing and other fraudulent schemes as described herein, created and maintained the opioid epidemic in Plaintiffs' communities, which is harmful and disruptive to and substantially and unreasonable annoys, injuriously affects, endangers, and interferes with the safety, health, morals, comfort, and general welfare of the public.

883. Defendants' nuisance-causing activities include selling or facilitating the sale of prescription opioids to the patients of Plaintiffs, as well as to unintended users, including children, people at risk of overdose or suicide, and criminals.

884. Defendants' nuisance-causing activities also include failing to implement effective controls and procedures in their supply chains to guard against theft, diversion and misuse of controlled substances, and their failure to adequately design and operate a system to detect, halt and report suspicious orders of controlled substances.

885. Defendants' activities unreasonably interfere with the economic rights of Plaintiffs.

886. The Defendants' interference with these rights of Plaintiffs is unreasonable because it:

a. Has harmed and will continue to harm the public health services of and public peace of Plaintiffs;

b. Has harmed and will continue to harm the communities and neighborhoods which Plaintiffs serve;

c. Is proscribed by statutes and regulation, including the CSA;

d. Is of a continuing nature and it has produced long-lasting effects;

e. Defendants have reason to know their conduct has a significant effect upon Plaintiffs; and

f. Has inflicted substantial costs on Plaintiffs.

887. The nuisance undermines public health, quality of life, and safety. It has resulted in high rates of addiction, overdoses, dysfunction, and despair within families and entire communities. It has created a public health crisis.

888. The resources of Plaintiffs are being unreasonably consumed in efforts to address the prescription drug abuse epidemic, thereby eliminating available resources needed in other health care areas.

889. Defendants' nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimately recognized societal interest in facilitating widespread opioid addiction and failing to identify, halt, and report suspicious opioid transactions.

890. Defendants knew of the public health hazard their conduct would create. It was foreseeable to Defendants that their conduct would unreasonably interfere with the ordinary comfort, use, and enjoyment of residents within the Commonwealth of Kentucky.

891. Defendants' conduct is unreasonable, intentional, unlawful, reckless, and/or negligent.

892. At all times, all Defendants possessed the right and ability to control the nuisance causing outflow of opioids from pharmacy locations or other points of sale. Distributor Defendants had the power to shut off the supply of illicit opioids to Plaintiffs and in the geographic areas

served by Plaintiffs.

893. As a direct and proximate result of the nuisance, Plaintiffs have sustained economic harm including, but not limited to, significant increased expenses for providing public health services, including but not limited to: (1) providing vaccinations and public health services related to public outbreaks of HIV, Hepatitis A, B, and C; (2) administering and operating needle exchange programs; (3) providing public safety relating to the opioid epidemic; (4) providing public health educational programs on preventing opioid addiction, abuse, and/or dependency; (5) providing prenatal services to infants and mothers with opioid-related medical conditions; (6) providing services for at least the first two years of a child's life, to children born with opioid-related medical conditions and children whose families suffer from opioid-related disabilities or incapacitation; and (7) providing services for at least the first two years of a child's life, to mothers and families of children suffering from opioid-related medical conditions. In short, the Defendants created a mess, leaving to the Plaintiffs and other district health departments the costs of cleaning it up. This is a classic nuisance.

894. As a result of Defendants' actions, Plaintiffs has suffered a special injury, different from that suffered by the public at large by individual users and by governmental entities, namely that Plaintiffs have provided uncompensated care for patients suffering from opioid-related conditions.

895. The public nuisance – i.e. the opioid epidemic – created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm and inconvenience can be abated.

896. Defendants should be required to pay the expenses Plaintiffs have incurred or will incur in the future to fully abate the nuisance.

897. Therefore, Plaintiffs demand judgment in its favor against the Defendants for injunctive relief, abatement of the public nuisance, and for damages in an amount to be determined by a jury, together with all cost of this action, including prejudgment interest, post-judgment interest, costs and expenses, attorney fees, and such other relief as this Court deems just and equitable.

COUNT IX: Unjust Enrichment
(Against All Defendants)

898. Plaintiffs repeat, reallege, and incorporates by reference all other paragraphs of this Complaint, as if fully set forth herein.

899. As a direct and proximate result of Defendants' conduct, Plaintiffs have suffered increased expenses for providing public health services, including but not limited to: (1) providing vaccinations and public health services related to public outbreaks of HIV, Hepatitis A, B, and C; (2) administering and operating needle exchange programs; (3) providing public safety relating to the opioid epidemic; (4) providing public health educational programs on preventing opioid addiction, abuse, and/or dependency; (5) providing prenatal services to infants and mothers with opioid-related medical conditions; (6) providing services for at least the first two years of a child's life, to children born with opioid-related medical conditions and children whose families suffer from opioid-related disabilities or incapacitation; and (7) providing services for at least the first two years of a child's life, to mothers and families of children suffering from opioid-related medical conditions. Plaintiffs thereby conferred benefits on Defendants because Defendants should bear the expense of treating these patients' opioid conditions. This is because Defendants created the opioid epidemic and the patients' opioid conditions, as described above.

900. Defendants appreciated and knew of this benefit because they knew their opioid

promotional and marketing policies would cause, and in fact have caused health departments throughout the United States and Kentucky to suffer increased expenses that Defendants are responsible for creating.

901. The circumstances under which Defendants accepted or retained the benefit, described above, were such as to make it inequitable for Defendants to retain the benefit without payment of its value.

902. As described above, the benefit was received and retained under such circumstances that it would be inequitable and unconscionable to permit Defendants to avoid payment therefor.

903. Defendants have therefore been unjustly enriched.

904. By reason of the foregoing, Defendants must disgorge their unjustly acquired profits and other monetary benefits resulting from its unlawful conduct and provide restitution to the Plaintiffs.

COUNT X: Fraud and Deceit
(Against All Defendants)

905. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein.

906. As alleged herein, Defendants violated their duty not to actively deceive by intentionally and unlawfully making knowingly false statements, and by intentionally and unlawfully omitting and/or concealing information.

907. Defendants made misrepresentations and failed to disclose material facts to physicians and consumers throughout Kentucky and the United States, to induce the physicians to prescribe and administer, and consumers to purchase and consume, opioids as set forth herein.

908. Specifically, the Marketing Defendants' knowingly deceptions during the relevant

period, which were intended to induce reliance, include but are not limited to:

b. Marketing Defendants' misrepresentations overstating the benefits of, and evidence for, the use of opioids in chronic pain;

c. Marketing Defendants' misrepresentations that the risks of long-term opioid use, especially the risk of addiction, were overblown;

d. Marketing Defendants' misrepresentations that opioid doses can be safely and effectively increased until pain relief is achieved;

e. Marketing Defendants' misrepresentations that signs of addiction were "pseudoaddiction" and thus reflected undertreated pain, which should be responded to with more opioids;

f. Marketing Defendants misrepresentations that screening tools effectively prevent addiction;

g. Marketing Defendants; misrepresentations concerning the comparative risks of NSAIDs and opioids;

h. Marketing Defendants' misrepresentations that opioids differ from NSAIDs in that opioids have no ceiling dose;

i. Marketing Defendants' misrepresentations that evidence supports the long-term use of opioids for chronic pain;

j. Marketing Defendants' misrepresentations that chronic opioid therapy would improve patients' function and quality of life;

k. Marketing Defendants' false portrayal of their efforts and/or commitment to rein in the diversion and abuse of opioids;

l. Marketing Defendants' misrepresentations that withdrawal is easily managed;

m. Purdue's and Endo's misrepresentations that alleged abuse-deterrent opioids reduce tampering and abuse;

n. Purdue's misrepresentations that OxyContin provides a full 12 hours of pain relief;

o. Purdue's misrepresentations that it cooperates with and supports efforts to prevent opioid abuse and diversion;

p. Mallinckrodt's misrepresentations that it meets or exceeds legal requirements for controlling against diversion of controlled substances it has been entrusted to handle;

q. Teva's misrepresentations that Actiq and Fentora were appropriate for treatment of non-cancer pain and its failure to disclose that Actiq and Fentora were not approved for such use;

r. Cephalon's unsubstantiated claims that Actiq and Fentora were appropriate for treatment of non-cancer pain;

s. Marketing Defendants' use of front groups to misrepresent that the deceptive statements from the sources described in this Complaint came from objective, independent sources;

t. Marketing Defendants' creation of a body of deceptive, misleading and unsupported medical and popular literature, advertisements, training materials, and speaker presentations about opioids that (1i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors; and,

u. Such other misrepresentations and deceptions outlined above.

909. By engaging in the acts and practices alleged herein, Marketing Defendants, in the relevant time period and with the intent that others rely on their omissions or suppression of information, omitted material facts that Marketing Defendants had a duty to disclose by virtue of these Defendants' other representations, including but not limited to:

a. Opioids are highly addictive and may result in overdose or death;

b. No credible scientific evidence supports the use of screening tools as a strategy for reducing abuse or diversion;

c. High dose opioids subject the user to greater risks of addiction, other injury, and/or death;

d. Opioids present the risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, dizziness, increased falls and fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interactions with alcohol or benzodiazepines; these omissions were made while Defendants exaggerated the risks of competing products such as NSAIDs;

e. Claims regarding the benefits of chronic opioid therapy lacked scientific support or were contrary to the scientific evidence;

f. Purdue's 12-hour OxyContin fails to last a full twelve hours in many patients;

g. Purdue and Endo's abuse-deterrent formulations are not designed to address, and have no effect on, the common route of abuse (oral), can be defeated with relative ease, and may increase overall abuse;

h. Marketing Defendants' failure to report suspicious prescribers and/or orders;

i. Cephalon's failure to disclose that Actiq and Fentora were not approved for non-cancer pain;

j. Marketing Defendants' failure to disclose their financial ties to and role in connection with KOLs, front groups, and deceptive literature and materials, as more fully described above; and

k. Such other omissions and concealments as described above in this Complaint.

910. In each of the circumstances described in the foregoing paragraph, Marketing Defendants knew that their failure to disclose rendered their prior representations untrue or misleading.

911. In addition, and independently, Marketing Defendants had a duty not to deceive Plaintiffs because Defendants had in their possession unique material knowledge that was unknown, and not knowable, to Plaintiffs, their agents, their communities, and the public.

912. Marketing Defendants intended and had reason to expect under the operative circumstances that Plaintiff, its agents, its community, physicians, and persons on whom Plaintiffs and their agents relied would be deceived by Defendants' statements, concealments, and conduct as alleged herein and that Plaintiffs would act or fail to act in reasonable reliance thereon.

913. Marketing Defendants intended that Plaintiffs, their agents, their communities, and persons upon whom Plaintiffs and their agents relied would rely on these Defendants' misrepresentations and omissions; Defendants intended and knew that this reasonable and rightful reliance would be induced by these Defendants' misrepresentations and omissions; and, Defendants intended and knew that such reliance would cause Plaintiffs to suffer loss.

914. The Marketing Defendants were not alone in this, the Distributor Defendants were also knowingly deceptive during the relevant period, and their deception was intended to induce

reliance. These deceptions include but are not limited to:

a. Acknowledgment of the Distributor Defendants by and through their front group, the HDMA, that distributors are at the center of a sophisticated supply chain and therefore, are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers;

b. Acknowledgment of the Distributor Defendants that because of their unique position within the "closed" system, they were to act as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market;

c. Cardinal Health claims to "lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse";

d. AmerisourceBergen took a same position as its counterpart within the industry and stated that it was "work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare to help find solutions that will support appropriate access while limiting misuse of controlled substances";

e. More holistically, Distributor Defendants misrepresented that not only do its members (Distributor Defendants) have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society; and

f. Such other omissions or concealments as described above in this Complaint.

915. By engaging in the acts and practices alleged herein, Distributor Defendants, in the relevant time period and with the intent that others rely on their omissions or suppression of

information, omitted material facts that Distributor Defendants had a duty to disclose by virtue of these Defendants' other representations, including but not limited to:

a. There being no legitimate medical purpose for the copious amounts of opioids shipped into and around Plaintiffs communities;

b. That they failed to report to the DEA suspicious orders;

c. That they failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical scientific and industrial channels by sales to certain customers;

d. That they failed to prevent against diversion from legitimate to non-legitimate channels;

e. That they failed to conduct meaningful due diligence to ensure that controlled substances were not diverted into other than legitimate channels;

f. That they failed to keep and maintain accurate records of Schedule II – V controlled substances; and

g. Such other omissions or concealments as alleged above in this Complaint.

916. Distributor Defendants intended and had reason to expect under the operative circumstances that Plaintiffs, their agents, their communities, and persons upon whom Plaintiffs relied would be deceived by Defendants' statements, concealments, and conduct as alleged herein and that Plaintiffs would act or fail to act in reasonable reliance thereon.

917. Distributor Defendants intended that Plaintiff, its agents, community, physicians, and persons on whom Plaintiffs and their agents relied would rely on these Defendants' misrepresentations and omissions; Defendants intended and knew that this reasonable and rightful reliance would be induced by these Defendants' misrepresentations and omissions; and,

Defendants intended and knew that such reliance would cause Plaintiffs to suffer loss.

918. Plaintiffs rightfully, reasonably, and justifiably relied on Marketing Defendants' representations and/or concealments, both directly and indirectly. As the Marketing Defendants knew or should have known Plaintiffs were directly and proximately injured as a result of this reliance, Plaintiffs' injuries were directly and proximately caused by this reliance.

919. As a result of these representations and/or omissions, Plaintiffs proceeded under the misapprehension that the opioid crisis was simply a result of conduct by persons other than Defendants. As a consequence, these Defendants prevented Plaintiffs from a timelier and more effective response to the opioid epidemic.

920. Defendants' false representations and omissions were material and were made and omitted intentionally and recklessly.

921. Defendants' misconduct alleged in this case is ongoing and persistent.

922. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort Plaintiffs would reasonably expect to occur and is not part of the normal and expected costs of a district health department's services. Plaintiffs allege wrongful acts which are neither discrete nor of the sort a district health department can reasonably expect.

923. As a direct and proximate result of Defendants' conduct, Plaintiffs have suffered actual injury and damages including, but not limited to, significant increased expenses for providing public health services, including but not limited to: (1) providing vaccinations and public health services related to public outbreaks of HIV, Hepatitis A, B, and C; (2) administering and operating needle exchange programs; (3) providing public safety relating to the opioid epidemic; (4) providing public health educational programs on preventing opioid addiction, abuse, and/or dependency; (5) providing prenatal services to

infants and mothers with opioid-related medical conditions; (6) providing services for at least the first two years of a child's life, to children born with opioid-related medical conditions and children whose families suffer from opioid-related disabilities or incapacitation; and (7) providing services for at least the first two years of a child's life, to mothers and families of children suffering from opioid-related medical conditions.

924. These Defendants' conduct was accompanied by wanton and willful disregard of person who foreseeably might be harmed by their acts and omissions.

925. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions had a great probability of causing substantial harm.

926. Plaintiffs have suffered monetary damages as aforesaid. As such Plaintiffs seek all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, including attorney fees and costs, and pre- and post-judgment interest.

COUNT XI: Conspiracy to Commit Fraud and Maintain a Nuisance (Against All Defendants)

927. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein.

928. Defendants engaged in a combination and an agreement to act in concert in their tortious and/or otherwise unlawful marketing of opioids and/or distribution of opioids in Kentucky and Plaintiffs' communities.

929. Defendants engaged in a civil conspiracy, in conjunction with their unlawful marketing of opioids and/or distribution of opioids into Kentucky and Plaintiffs' communities, to commit fraud and misrepresentation and maintain a public nuisance.

930. Defendants each conspired with various KOLs and Front Groups to commit unlawful or lawful acts in an unlawful manner. Defendants and the various KOLs and Front Groups with which each of them was allied, knowingly and voluntarily agreed to engage in unfair and deceptive practices to promote and distribute opioids for the treatment of chronic pain by making and disseminating false, unsubstantiated, and misleading statements and misrepresentations to prescribers and consumers. Defendants enlisted various KOLs and Front Groups to make and disseminate these statements in furtherance of their common strategy to increase the sale and distribution of opioids, and Defendants—along with the KOLs and Front Groups with whom each of them conspired—knew that the statements they made and disseminated served this purpose.

931. By engaging in the conduct described in this Complaint, Defendant Cephalon agreed with Front Groups FSMB and APF that they would deceptively promote the risks, benefits and superiority of opioid therapy. As part of its agreements with FSMB and APF, Cephalon provided support for FSMB's and APF's deceptive statements promoting opioids and FSMB and APF used that support to more broadly disseminate deceptive messaging promoting opioids, which would benefit Cephalon's drugs. *Responsible Opioid Prescribing* (Cephalon and FSMB) and *Treatment Options: A Guide for People Living with Pain* (Cephalon and APF) are publications that contained a number of deceptive statements about opioids as outlined *supra.* They are products of these conspiracies, and the collaboration between Cephalon and each of these entities in creating and disseminating these publications is further evidence of each conspiracy's existence.

932. By engaging in the conduct described in this Complaint, Defendant Endo agreed with Front Groups APF, NICP, AGS and FSMB that they would deceptively promote the risks, benefits, and superiority of opioid therapy. As part of its agreements with APF, NIPC, AGS and FSMB, Endo provided support for APF, NICP, AGS and FSMB's deceptive statements promoting

opioids and APF, NICP, AGS and FSMB used that support to more broadly disseminate deceptive messaging promoting opioids, which would benefit Endo's drugs. *Persistent Pain in the Older Adult* (Endo, APF, and NIPC), *Persistent Pain in the Older Patient* (Endo, APF, and NIPC), *Painknowledge.com* (Endo, APF, and NIPC), *Exit Wounds* (Endo and APF), *Pharmacological Management of Persistent Pain in Older Persons* (Endo and AGS), and *Responsible Opioid Prescribing* (Endo and FSMB) are publications, CMEs, and websites that contained a number of deceptive statements about opioids as outlined *supra.* They are products of these conspiracies, and the collaboration between Endo and each of these entities in creating and disseminating these publication, CMEs, and websites is further evidence of each conspiracy's existence.

933. By engaging in the conduct described in this Complaint, Defendant Janssen agreed with Front Groups AAPM, AGS and APF that they would deceptively promote the risks, benefits, and superiority of opioid therapy. As part of its agreements with AAPM, AGS, and APF, Janssen provided support for AAPM, AGS, and APF's deceptive statements promoting opioids and Conrad & Associates LLC, Medical Writer X, AAPM, AGS, and APF used that support to more broadly disseminate deceptive messaging promoting opioids, which would benefit Janssen's drugs. *Finding Relief: Pain Management for Older Adults* (Janssen, AAPM, and AGS), a CME promoting the *Pharmacological Management of Persistent Pain in Older Persons* (Janssen and APF), the *Let's Talk Pain* website (Janssen and APF), and *Exit Wounds* (Janssen and APF) are publications, CMEs, and websites that contained a number of deceptive statements about opioids as outlined *supra*. They are products of these conspiracies and the collaboration between Janssen and each of these entities in creating and disseminating these publications is further evidence of each conspiracy's existence.

934. By engaging in the conduct described in this Complaint, Defendant Purdue agreed

with Front Groups APF, FDMB, and AGS that they would deceptively promote the risks, benefits, and superiority of opioid therapy. As part of its agreements with APF, FSMB, and AGS, Purdue provided support for APF, FSMB, and AGS's deceptive statements promoting opioids and APF, FSMB, and AGS used that support to more broadly disseminate deceptive messaging promoting opioids, which would benefit Purdue's drugs. The *Partners Against Pain* website (Purdue and APF), *A Policymaker's Guide to Understanding Pain & Its Management* (Purdue and APF), *Treatment Options: A Guide for People Living with Pain* (Purdue and APF), *Exit Wounds* (Purdue and APF),[372] *Responsible Opioid Prescribing* (Purdue and FSMB), and a CME promoting the *Pharmacological Management of Persistent Pain in Older Persons* (Purdue and AGS) are publications, CMEs, and websites that contained a number of deceptive statements about opioids as outlined *supra*. They are products of these conspiracies, and the collaboration between Purdue and each of these entities in creating and disseminating these publications, CME's and websites is further evidence of each conspiracy's existence.

935. Each of the participants to the conspiracies outlined above was aware of the misleading nature of the statements they planned to issue and of the role they played in each scheme to deceptively promote opioids as appropriate for the treatment of chronic pain. These Defendants and third parties nevertheless agreed to misrepresent the risks, benefits, and superiority of using opioids to Plaintiffs in return for increased pharmaceutical sales, financial contributions, reputational enhancements, and other benefits.

936. Each of the participants to the conspiracies outlined above was aware of the nuisance resulting from their conduct, and agreed to continue the practices described above that

[372] Purdue's collaboration with APF through APF's "Corporate Roundtable" and Purdue and APF's active collaboration in running PCF constitute additional evidence of the conspiracy between Purdue and APF to deceptively promote opioids.

resulted in the maintenance of that nuisance.

937. Distributor Defendants utilized their membership in the HDA and other forms of collaboration to form agreements about their approach to their duties under the CSA to report suspicious orders. The Defendants overwhelmingly agreed on the same approach – to fail to identify, report or halt suspicious opioid orders, and fail to prevent diversion. Defendants' agreement to restrict reporting provided an added layer of insulation from DEA scrutiny for the entire industry as Defendants were thus collectively responsible for each other's compliance with their reporting obligations. Defendants were aware, both individually and collectively aware of the suspicious orders that flowed directly from Defendants' facilities.

938. Defendants knew that their own conduct could be reported by other Defendants and that their failure to report suspicious orders they filled could be brought to the DEA's attention. As a result, Defendants had an incentive to communicate with each other about the reporting or suspicious orders to ensure consistency in their dealings with DEA.

939. The Defendants also worked together to ensure that the opioid quotas allowed by the DEA remained artificially high and ensured that suspicious orders were not reported to the DEA in order to ensure that the DEA had no basis for refusing to increase or decrease production quotas due to diversion.

940. The Defendants further worked together in their unlawful failure to act to prevent diversion and failure to monitor for, report, and prevent suspicious order of opioids.

941. The desired consistency, and collective end goal was achieved. Defendants achieved blockbuster profits through higher opioid sales by orchestrating the unimpeded flow of opioids.

942. By reason of Defendants' unlawful acts, Plaintiffs have been damaged and continue

to be damaged by paying the costs of Defendants externalities and has suffered additional damages for the costs of providing and using opioids long-term to treat chronic pain.

943. Defendants acted with a common understanding or design to commit unlawful acts, as alleged herein, acted purposely, without a reasonable or lawful excuse, which directly caused the injuries alleged herein.

944. Defendants acted with malice, purposely, intentionally, unlawfully, and without a reasonable or lawful excuse.

945. As outlined above, Defendants played an active role in determining the substance of the misleading messages issued by KOLs and Front Groups, including by providing content themselves, editing and approving content developed by their co-conspirators, and providing slide decks for speaking engagements. Defendants further ensured that these misstatements were widely disseminated, by both distributing the misstatements themselves and providing their co-conspirators with funding and other assistance with distribution. The result was and unrelenting stream of misleading information about compliance with state and federal legislation as related to opioid distribution, and the risks, benefits, and superiority of using opioids to treat chronic pain from sources Defendants knew were trusted by prescribers and consumers. Defendants exercised direct editorial control over most of these statements. However, even if Defendants did not directly disseminate or control the content of these misleading statements, they are liable for conspiring with the third parties who did.

946. Defendants conduct in furtherance of the conspiracy described herein was not mere parallel conduct because each Defendant acted directly against their commercial interests in not reporting the unlawful distribution practices of their competitors to the authorities, which they had a legal duty to do. Each Defendant acted against their commercial interests in this regard due to an

actual or tacit agreement between the Defendants that they would not report each other to the authorities so they could all continue to engage in their unlawful conduct.

947. Defendants' conspiracy, and Defendants' actions and omissions in furtherance thereof, caused the direct and foreseeable losses alleged herein.

948. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions had a great probability of causing substantial harm.

949. Defendants' misconduct alleged in this case is ongoing and persistent.

950. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergent of the sort a district health department would reasonably expect to occur and is not part of the normal and expected costs of a district health department's healthcare services. Plaintiffs allege wrongful acts which are neither discrete nor of the sort a district health department can reasonably expect.

951. Plaintiffs have incurred expenditures for special programs over and above ordinary healthcare services.

952. Because of Defendants dissemination of false information and misleading information of opioid risks, benefits, and sustainability for chronic pain, and false and misleading statements regarding compliance with Kentucky law concerning the distribution of opioids, Defendants are responsible for the costs.

953. Plaintiffs therefore request this Court to enter an order awarding judgment in its favor against Defendants, compelling Defendants to pay the direct and consequential damages, and awarding Plaintiffs such other, further, and different relief as this Court may deem just and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray that this Court grant the following relief:

1. certify Kentucky River's claims for class action under Rules 23(b)(2) and 23(b)(3) of the Federal Rules of Civil Procedure;
2. permit a jury trial on all issues so triable under Rule 38 of the Federal Rules of Civil Procedure;
3. enter Judgment in favor of the Plaintiffs in a final order against each of the Defendants;
4. enjoin the Defendants and their employees, officers, directors, agents, successors, assignees, merged or acquired predecessors, parent or controlling entities, subsidiaries, and all other persons acting in concert or participation with it, from engaging in unfair or deceptive practices in violation of law and ordering temporary, preliminary or permanent injunction;
5. order that Defendants abate the ongoing public nuisance caused by the opioid epidemic;
6. order that Defendants fully compensate the Plaintiffs for the costs to abate the ongoing public nuisance caused by the opioid epidemic;
7. order Defendants to establish and fund an "abatement fund" for the purposes of abating the opioid nuisance;
8. award actual damages, treble damages, punitive damages, injunctive and equitable relief, forfeiture as deemed proper by the Court, and attorneys' fees and all costs and expenses of suit pursuant to Plaintiffs' RICO claims;

9. award Plaintiffs the damages caused to them by the opioid epidemic, including but not limited to: (1) providing vaccinations and public health services related to public outbreaks of HIV, Hepatitis A, B, and C; (2) administering and operating needle exchange programs; (3) providing public safety relating to the opioid epidemic; (4) providing public health educational programs on preventing opioid addiction, abuse, and/or dependency; (5) providing prenatal services to infants and mothers with opioid-related medical conditions; (6) providing services for at least the first two years of a child's life, to children born with opioid-related medical conditions and children whose families suffer from opioid-related disabilities or incapacitation; and (7) providing services for at least the first two years of a child's life, to mothers and families of children suffering from opioid-related medical conditions;

10. enter judgment against the Defendants requiring Defendants to pay punitive damages;

11. grant the Plaintiffs the costs of investigation, reasonable attorneys' fees, and all costs and expenses;

12. award Plaintiffs pre-judgment and post-judgment interest; and

13. award all other relief as provided by law and/or as the Court deems appropriate and just under the circumstances.

JURY DEMAND

Plaintiffs demand a trial by jury on all issues so triable.

Respectfully submitted,

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